APPENDIX A

Annotated Bibliography

Annotated Bibliography: Summary of Risk Assessment Requirements and Guidance

1.0 Statutory and Regulatory Requirements

1.1 Comprehensive Environmental Response, Compensation, and Liability Act *(CERCLA). 1980. PL 96-510.*

In 1980, Congress enacted the Comprehensive, Environmental Response, Compensation, and Liability Act (CERCLA), commonly referred to as Superfund in response to the dangers posed by sudden or otherwise uncontrolled releases of hazardous substances, pollutants, or contaminants into the environment. This statute created the Superfund program, and the need to conduct baseline risk assessments. CERCLA authorized 1.6 billion dollars over five years for a comprehensive program to clean up the worst abandoned or inactive waste sites in the nation. The National Contingency Plan (NCP), the implementing regulation of CERCLA, provides the organizational structure and procedures for preparing and responding to releases of hazardous substances, pollutants, and contaminants. The NCP is codified in 40 CFR 300.

1.2 CERCLA as Amended by SARA.
Superfund Amendments and Reauthorization Act (SARA). 1986. PL 99-499.

The reauthorization of CERCLA occurred in 1986. These amendments, known as the Superfund Amendments and Reauthorization Act (SARA), strengthen the Environmental Protection Agency's (EPA's) mandate to focus on permanent cleanups at Superfund sites, involve the public in decision processes at sites, and encourage States and Federally recognized Indian tribes to actively participate as partners with EPA to address these sites. SARA also expanded EPA's research and development in the area of alternative technologies. The changes to CERCLA Sections 104 (Response Authorities) and 121 (Cleanup Standards) had the greatest impact on the remedial investigation/feasibility study process. Section 121 cleanup standards state a strong preference for remedies that are reliable and provide long-term protection. Section 121(b) remedy selection strategies

- prefer remedial actions that employ treatment that permanently and significantly reduce the volume, toxicity, or mobility of hazardous substances, pollutants, and contaminant,

- discourage the use of off-site transport and disposal without treatment as the least favored alternative where practicable treatment technologies are available; and

- assess the use of alternative treatment technologies or resource recovery technologies and promote their use to the maximum extent possible.

Section 121(c) requires a review of remedial actions at five- year intervals after the initial remedial action as long as hazardous substances, pollutants, or contaminants that may pose a threat to human health or the environment remain at the site. If it is determined that the action has not provided protection to human health and the environment then further remedial action must be considered.

Section 121(d) requires that all Superfund remedial actions meet any Federal standards, requirements, criteria, or limitations that are determined to be legally applicable or relevant and appropriate requirements (ARARs). A provision is included in this section that if State ARARs are more stringent than Federal requirements, the State standards must be followed.

Section 104 of CERCLA requires the Agency for Toxic Substances and Disease Registry (ASTDR) to conduct a health assessment, which is qualitative by nature, for each Superfund site. This health assessment should be distinguished from the EPA Human Health Evaluation which is more quantitative in nature. CERCLA Section 104(i)(5)(F) defines health assessment as follows:

> The term "health assessment" shall include preliminary assessments of the potential risks to human health posed by individual sites and facilities, based on such factors as the nature and extent of contamination, the existence of potential pathways of human exposure (including ground and surface water contamination, air emissions, and food chain contamination), the size and potential susceptibility of the community within the likely pathways of exposure, the comparison of expected human exposure levels to the short-term and long-term health effects associated with identified hazardous substances and any available recommended exposure or tolerance limits for such hazardous substances, and the comparison of existing morbidity and mortality data on diseases that may be associated with the observed levels of exposure. The Administrator of ATSDR shall use appropriate data, risk assessments, risk evaluations, and studies available from the Administrator of EPA.

An ATSDR health assessment and the traditional risk assessment should be distinguished from each other.

- The health assessment is qualitative in nature, site specific, and focuses on medical and public health perspectives. Exposure to contaminants are discussed in terms of especially sensitive populations, mechanisms of toxic chemical action, and possible disease outcomes.

- Risk assessments, the framework of EPA's human health evaluation, differ from health assessments in that they are quantitative, chemical-oriented characterizations that use statistical and biological models to calculate numerical estimates of risk to health.

Both health and risk assessments use data from human epidemiological investigations when available. If human toxicological data are unavailable, the assessments rely on results from animal toxicology studies.

1.3 The National Oil and Hazardous Substances Pollution Contingency Plan.

U.S. Environmental Protection Agency. Washington, D.C. 1985. 50 FR 47912.

The National Contingency Plan (NCP) provides the organizational structure and procedures for preparing and responding to discharges of oil and releases of hazardous substances, pollutants, and contaminants. The NCP is required by Section 105 of CERCLA and by Section 311 of the Clean Water Act. The NCP was published on November 20, 1985, and was codified at 40 CFR 300.

Section 300.68 (Remedial Action) was written to implement objectives of the Superfund Remedial Action program. Objectives of the remedial action specified in the 1985 NCP are "to determine the nature and extent of the threat presented by the release and to evaluate proposed remedies. This includes sampling, monitoring, and exposure assessment, as necessary, and includes the gathering of sufficient information to determine the necessity for and proposed extent of remedial action." A remedial investigation/feasibility study (RI/FS) shall be undertaken by the lead agent y. Scoping of response actions includes an initial analysis to indicate the extent to which the release or threat of release may pose a hazard to public health or welfare or the environment. In determining whether and what type of remedial and/or removal actions will be considered the following will be assessed:

- population, environmental, and welfare concerns at risk;
- routes of exposure;
- amount, concentration, hazardous properties, environmental fate and transport (e.g., ability and opportunities to bioaccumulate, persistence, mobility, etc.), and form of the substance(s) present;
- hydrogeological factors;
- current and potential ground water use;
- climate;
- the extent to which the source can be adequately identified and characterized;
- whether substances at the site may be reused or recycled;
- the likelihood of future releases if the substances remain on-site;
- the extent to which natural or manmade barriers currently contain the substances, and the adequacy of the barriers;

- the extent to which the substances have migrated or are expected to migrate from the area of their original location, or new location if relocated, and whether future migration may pose a threat to public health, welfare, or the environment;

- the extent to which Federal environmental and public health requirements are applicable or relevant and appropriate to the specific site;

- the extent to which contamination levels exceed applicable or relevant and appropriate Federal requirements or other Federal criteria, advisories, and guidance and State standards;

- contribution of the contamination to air, land, water, and/or food chain contamination problems; and

- ability of the responsible party to implement and maintain the remedy until the threat is permanently abated.

1.4 Final Rule of the National Oil and Hazardous Substances Pollution Contingency Plan.

U.S. Environmental Protection Agency. Washington, D.C. 1990. 55 FR 8666.

The National Contingency Plan [NCP] provides the organizational structure and procedures for preparing and responding to discharges of oil and releases of hazardous substances, pollutants, and contaminants. The NCP is required by Section 105 of CERCLA and by Section 311 of the Clean Water Act. The NCP was published on November 20, 1985 and was codified at 40 CFR 300. A revised version was proposed on December 21, 1988, in response to SARA. The NCP was revised and published in the Federal Register on March 8, 1990. The primary purpose of this final rule was to implement regulatory changes necessitated by SARA and to resolve issues that commentors raised about the proposed rule (1988) and the original NCP.

Section 300.430 (Remedial Investigation-Baseline Risk Assessment) was written to clarify and implement objectives of the Superfund Risk Assessment program. Following are the objectives of the baseline risk assessment (BRA) as specified in the 1990 NCP:

- to provide an analysis of baseline risk (i.e., the risks that exist if no remediation or institutional controls are applied to a site); and

- to use the risks and exposure pathways developed in the BRA to target chemical concentrations associated with levels of risk that will be adequately protective of human health for a particular site.

The revised NCP clarifies several issues regarding the baseline risk assessment:

- The NCP clarifies the relation of ARARs to the BRA; the identification of ARARs is not part of the BRA; it is a separate part of the RI. Nevertheless, ARARs should be addressed consistently in the risk assessment, the remedial investigation/feasibility study, and remedy selection.

- Risk assessments are to be performed on a site-specific basis. This is consistent with CERCLA Section 104(i)(6), which requires the Agency for Toxic Substances and Disease Registry (ATSDR) to perform health assessments for facilities on the proposed and final National Priorities List.

- EPA stated that the reasonable maximum exposure (RME) scenario will still be used by the Agency but it is not considering it as a requirement in the NCP. The RME scenario is a product of factors, such as contaminant concentration and exposure frequency and duration, that are an appropriate mix of values that reflect averages and 95th percentile distributions.

- In considering land use, the risk assessment will consider reasonable future land use from land use development patterns, and such land use assumptions may be associated with the highest (most significant) risk These considerations will lead to the assumption of residential use as the future land use in many cases.

- EPA clarifies the role of the toxicity assessment component of Superfund risk assessment. Toxicity assessment considers the following: (1) the types of adverse health or environmental effects associated with chemical exposures, (2) the relationship between magnitude of exposure and adverse effects, and (3) related uncertainties such as weight of evidence for chemical carcinogenicity in humans.

- Proposed Section 300.430(d)(4) of the rule has been clarified to indicate that both current and potential exposures and risks are to be considered in the RA. No other changes have been made to the rule on risk assessment,

- In Subpart E, the acceptable cancer range in Section 300.430(e)(2) has been modified from the proposed 10^{-4} to 10^{-6}. EPA's approach allows a pragmatic and flexible evaluation of potential remedies at a site while still protecting human health and the environment. This approach emphasizes the use of 10^{-6} as the point of departure while allowing site- or remedy-specific factors, including potential future uses, to enter the evaluation of what is appropriate at a given site.

- Subpart K will provide a roadmap to those requirements in the NCP that Federal agencies must follow when conducting CERCLA response actions where either the release is on, or the sole source of the release is from, any facility or vessel under their jurisdiction, custody, or control.

2.0 Risk Assessment Guidance

2.1 The Effects on Populations of Exposure to Low Levels of Ionizing Radiation (BEIR III).

National Academy of Sciences (NAS). 1980. National Academy Press. Washington D.C.

This report was prepared by the Committee on the Biological Effects of Ionizing Radiation (BEIR). It deals with the scientific basis of effects of low-dose radiation and encompasses a review and evaluation of scientific knowledge developed since the first BEIR report concerning radiation exposure of human populations. The report concentrates primarily on the long-term somatic and genetic risks to people exposed to ionizing radiation at low doses. Somatic effects also discussed in the report include developmental abnormalities of varying severity caused by fetal or embryonic exposure. This report was utilized in Chapter 10 of Risk Assessment Guidance for Superfund (RAGS) to help in the evaluation of risks posed by exposure to low levels of ionizing radiation, This report was updated by BEIR V. BEIR V is the current report that should be used for evaluating risks from low levels of ionizing radiation.

2.2 Chemical Carcinogens: a Review of the Science and its Associated Principles.

U.S. Environmental Protection Agency. 1985. Office of Science and Technology Policy (OSTP). Washington, D.C.

This document has two stated purposes: (1) to articulate a view of chemical carcinogenesis that scientists generally hold in common today and (2) to draw upon this understanding to compose a series of general principles that can be used to establish guidelines for assessing carcinogenic risk. The document states that "elucidation of the basic mechanisms underlying cancer and the identification of cancer-causing agents and conditions, when coupled to research aimed at identifying and evaluating the problems created by such agents, should provide the optimal administrative bases for making sound and reasonable judgments. "

Part I of this document lays out 31 principles that can be used by various Federal agencies in reviewing their own specific guidelines for performing cancer risk assessments. Part II of the document contains six chapters on the scientific background that went into establishing the 31 principles.

The principles outlined in this document, which form the basis for EPA's risk assessment of carcinogens, also have been used in several other documents including Guidelines for Carcinogen Risk Assessment and Risk Assessment Guidance for Superfund. Volume 1: Human Health Evaluation Manual (Part A).

2.3 Guidance on Remedial Investigations under CERCLA (RI Guide).

U.S. Environmental Protection Agency. 1985. Office of Solid Waste and Emergency Response. Washington, D.C. EPA 540/G-85/002

This document provides guidance on the conduct of remedial investigations (RIs). It provides personnel conducting remedial investigations the means to plan, prepare, conduct, and conclude RIs. The

- The NCP clarifies the relation of ARARs to the BRA; the identification of ARARs is not part of the BRA; it is a separate part of the RI. Nevertheless, ARARs should be addressed consistently in the risk assessment, the remedial investigation/feasibility study, and remedy selection.

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This document provides guidance on the conduct of remedial investigations (RIs). It provides personnel conducting remedial investigations the means to plan, prepare, conduct, and conclude RIs. The document describes the essential steps in the RI process. The remedial investigation is used to characterize a hazardous waste site. Information from the site characterization is used in the toxicity and exposure assessment phases of the baseline risk assessment. Thus, an improperly conducted RI will result in an inaccurate risk assessment. This document was used in the development of the Superfund Public Health Evaluation Manual. It was also revised and incorporated with the Guidance on Feasibility Studies Under CERCLA into the Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA.

2.4 Guidance on Feasibility Studies under CERCLA.

U.S. Environmental Protection Agency. 1985. Office of Solid Waste and Emergency Response. Washington, D. C. EPA 540/G-85/002.

This document, details the process for identifying, evaluating, and selecting remedial action alternatives for hazardous waste sites. Results from the baseline risk assessment assist in determining the scope of the remedial action alternatives. Low risks generally result in more simple remedial action alternatives, while higher risks will generally involve more complicated alternatives. The analysis of the alternatives involves five areas: engineering, institutional, public health, environmental, and cost. The engineering analysis investigates the constructability and reliability y of the various alternatives. The institutional analysis evaluates the alternatives in terms of the Federal, State, or local requirements, advisories, or guidance that must be considered to protect public health, welfare, and the environment. The public health analysis includes baseline site evaluation, exposure assessment standards analysis, short- and long-term effects of each alternative, and endangerment assessment. The environmental evaluation includes assessment of adverse impacts if no action is taken and the short- and long-term effects of the remedial action alternatives. The cost analysis evaluates capital and operating costs, and involves present worth and sensitivity analyses. These areas are addressed in separate chapters within the document- It was also revised and incorporated with the Guidance on Remedial Investigations Under CERCLA into the Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA.

2.5 Guidelines for Estimating Exposures.
U.S. Environmental Protection Agency. 1986. Office of Health and Environmental Assessment. Washington, D.C. 51 FR 34042;

Guidelines for Carcinogen Risk Assessment.
U.S. Environmental Protection Agency. 1986. Office of Health and Environmental Assessment. Washington, D.C. 51 FR 33992;

Guidelines for Mutagenicity Risk Assessment.
U.S. Environmental Protection *Agency. 1986. Office of Health and Environmental Assessment. Washington, D.C. 51 FR 34006;*

Guidelines for the Health Assessment of Suspect Developmental Toxicants.
U.S. Environmental Protection Agency. 1986. Office of Health and Environmental Assessment. Washington D. C. 51 FR 34028;

Guidelines for the Health Risk Assessment of Chemical Mixtures.
U.S. Environmental Protection Agency. 1986. Office of Health and Environmental Assessment. Washington, D. C. 51 FR 34014.

These five guidelines were published together and were intended to be used in assessing the health risks of environmental pollutants. They set forth principles and procedures to guide scientists in the conduct of Agency risk assessments, and they emphasize that risk assessments will be conducted on a case-by-case basis. When the National Research Council (NRC) of the National Academy of Sciences (NAS) published its book entitled Risk Assessment in the Federal Government: Managing the Process in 1983, they recommended that Federal regulatory agencies ensure that the risk assessment process be maintained as a scientific effort separate from risk management. All five of these guidelines support this recommendation. As outlined above, the risk assessment process involves four steps: data collection and evaluation (hazard identification), toxicity/dose-response assessment, exposure assessment and risk characterization. The last four of these guidelines provide guidance on the entire risk assessment process in their respective subject areas. The first only addresses the exposure assessment step in the risk assessment process. All five guideline documents have been used in developing other documents which include the Superfund Exposure Assessment Manual, Exposure Factors Handbook and Risk Assessment Guidance for Superfund.

2.6 Superfund Public Health Evaluation Manual (SPHEM).
U.S. Environmental Protection Agency. 1986. Office of Emergency and Remedial Response. Washington, D.C. EPA 5401/1-86/060.

This document was developed to supplement Chapter 5 of the Guidance on Feasibility Studies Under CERCLA. That guidance described what the public health evaluation process was, but it did not describe how to conduct the evaluation. It is the first document published that describes how to conduct a baseline risk assessment. This document also addresses the public health analysis of remedial alternatives. The procedures in this manual were designed to conform to the five guidelines listed in 2.5 above.

2.7 Superfund Exposure Assessment Manual (SEAM).

U.S. Environmental Protection Agency. 1988. Office of Remedial Response. Washington, D.C. EPA 5401/1-88/OO1.

The analytical procedures outlined in this document provide a complete, integrated framework for the assessment of exposure to contaminants” at or migrating from uncontrolled hazardous waste sites. The application of both monitoring and modeling procedures to the exposure assessment process is outlined This process considers all contaminant releases and exposure routes. The analytical protocol is structured into five segments:

1. analysis of contaminant release-s from a site into environmental media;
2. evaluation of the transport and environmental fate of the chemicals released;
3. identification, enumeration, and characterization of potential y exposed populations;
4. integrated exposure analysis; and
5. uncertainty analysis.

The analytical protocol provided by SEAM was designed specifically to support the baseline risk assessment process as called for by Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA (USEPA, 1988) and as outlined by the Superfund Public Health Evaluation Manual (USEPA, 1986f). It continues to constitute a key technical resource supporting development of baseline risk assessments as currently directed by Risk Assessment Guidance for Superfund (USEPA, 1989a).

2.8 Recommended Procedures for Implementation of Superfund Risk Assessment Guidelines

U.S. Environmental Protection Agency. 1988. U.S. *EPA Region IX. In. Exposure Assessment at Superfund Sites.* U.S. *Environmental Protection Agency, Environmental Monitoring Systems Laboratory. Las Vegas, NV, EPA 600/X-89/381 1989.*

Region IX published 38 recommendations to assist risk assessors in completing a baseline risk assessment, particularly for Region IX. The recommendations covered the areas of exposure and toxicity assessment, indicator chemical identification, environmental fate and transport of chemicals, data presentation, data gaps, and uncertainty. These recommendations were incorporated and published in Exposure Assessment at Superfund Sites. Many of the recommendations made in this document are still currently followed.

2.9 Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA.

U.S. Environmental Protection Agency. 1988. Office of Emergency and Remedial Response. Washington, D.C. OSWER Directive 9355.3-01.

This guidance manual combined and replaced the Guidance on Remedial Investigations Under CERCLA and Guidance on Feasibility Studies Under CERCLA. It incorporated the changes made to CERCLA by SARA. It gave a brief overview of the steps involved the baseline risk assessment and stated that the risk assessment provides "the basis for determining whether or not remedial action is necessary and the justification for performing remedial actions. " The results of the BRA will determine the scope of the feasibility study.

2.10 Proposed Guidelines for Assessing Female Reproductive Risk.

U.S. Environmental Protection Agency. 1988. Office of Health and Environmental Assessment. Washington, D.C. 53 FR 24834;

Proposed Guidelines for Assessing Male Reproductive Risk.

U.S. Environmental Protection Agency. 1988. Office of Health and Environmental Assessment. Washington, D. C. 53 FR 24850.

These guidelines describe the procedures to follow in evaluating the potential toxicity of environmental agents to the human male and female reproductive systems. They provide guidance for the interpretation and analysis of studies conducted according to the testing guidelines, for conducting risk assessments and information on other types of studies available when reviewing data on particular agents. The female reproductive guidelines discuss how events in the female reproductive cycle are closely interrelated and how alterations in one event in the cycle can cause alterations in other events in the cycle. The male reproductive guidelines focus on male reproductive function as it relates to sexual behavior, fertility, and male-mediated pregnancy outcomes, plus effects on processes that can affect those functions directly. These are two of three guidelines issued for assessing non-cancer health effects. hey are intended to be utilized for the non-cancer toxicity assessment component of the BRA outlined in the Risk Assessment Guidance for Superfund.

2.11 Health Risks of Radon and Other Internally Deposited Alpha-emitters (BEIR IV).

National Academy of Sciences (NAS). 1988. BEIR IV. National Academy Press. Washington, D. C.

This report addresses demonstrated and potential health effects of exposure of human populations to internally deposited alpha-emitting radionuclide and their decay products. The report is divided into the following main categories

- carcinogenic and other health effects of radon, radium, thorium, polonium, uranium, and the transuranic radionuclide;

- genetic, teratogenic, and fetal effects of internally deposited alpha-emitting radionuclide, and
- the scientific bases and mechanisms underlying the biological and health effects, including the relevant physics and dosimetry, radiobiology, anatomy, and physiology.

Where possible, the report presents quantitative risk estimates for cancer induction. This report is utilized in Chapter 10 of Risk Assessment Guidance for Superfund to help in the evaluation of risks posed by internally deposited alpha-emitters.

2.12 Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual (Part A)

U.S. Environmental Protection Agency. 1989. Office of Emergency and Remedial Response. Washington, D. C. EPA 540/1-89/002.

Risk Assessment Guidance for Superfund (RAGS) constitutes the present conceptual framework for CERCLA risk assessments. All four steps (data collection and evaluation, exposure assessment, toxicity assessment, and risk characterization) in that process are discussed in detail. The four steps are briefly discussed in Chapter 1. This is the primary guidance document used for conducting baseline risk assessments. The other two documents in this series (see Sections 2.21 and 2.22) discuss remediation goals and alternatives. This document revised and replaced SPHEM. Other guidance currently being used in the development of baseline risk assessments are used in conjunction with the overall protocol outlined in RAGS.

2.13 Exposure Factors Handbook (EFH). U.S. Environmental Protection Agency. 1989.

Office of Health and Environmental Assessment. Washington, D. C. EPA 600/8-89/63.

The purpose of this handbook was to provide a summary of the available data on various factors used in exposure assessments including drinking water consumption; consumption rates of foods including fruits, vegetables, beef, dairy products, and fish; soil ingestion; inhalation rate; skin area; lifetime; activity patterns; and body weight. A number of specific exposure scenarios are identified, along with recommendations for default values to use when site-specific data are not available. Additionally, basic equations using these parameters to estimate exposure levels are also presented for each scenario. Monte Carlo and sensitivity analysis procedures for assessing the uncertainties in exposure assessments are also addressed. Some of the procedures presented in this document were incorporated into RAGS.

2.14 Supplemental Manual to Risk Assessment Guidance for the Superfund Program (SMRAGSP).

U.S. Environmental Protection Agency. 1989. U.S. EPA Region I: EPA 901/5-89-001.

This Region I manual is intended to supplement the Superfund Public Health Evaluation Manual, the Superfund Exposure Assessment Manual, and the Endangerment Assessment Handbook Region I experience with risk assessments showed that the assessments had wide variability y with respect to structure, content, and quality. Therefore, the overall goal of this manual is to improve the quality and consistency of risk assessments performed in Region I. The guidance is intended to be as practical and useful as possible, consequently, it is very explicit on technical matters in all four areas of the baseline risk assessment process.

2.15 Risk Assessment Methodology - Environmental Impact Statement - NESHAPs for Radionuclide - Background Information Document - Volume 1.

U.S. Environmental Protection Agency. 1989. Office of Radiation Programs. Washington, D. C. EPA 520/1-89-005.

This background document involves the National Emission Standards for Hazardous Air Pollutants (NESHAPs). Even though this rule is under the Clean Air Act, it provides information on methods used in radiation risk assessment. This background document provides information on EPA's radiation protection programs and a detailed description of EPA's procedures and methods for estimating radiation doses and risk due to radionuclide emissions to the air. Appendix A describes the environmental transfer factors used in the dose assessment models. Appendix B describes the mechanics of the life table implementation used to estimate risk. Appendix C presents an overview of the quantitative uncertainty analysis techniques currently under review.

2.16 International Commission on Radiological Protection: Recommendations of the Commission - 1990.

International Commission on Radiological Protection (ICRP). ICRP/90/G-01.

This report is intended to be of help to regulatory and advisory authorities at national, regional, and international levels, mainly by providing guidance on the fundamental principles on which appropriate radiological protection can be based. The report is divided into the following subjects:

- the physical quantities and units used in radiological protection and the biological effects of radiation,
- the fundamentals of radiological protection,
- the Commission's main recommendations, and
- the practical implementation of the recommendations.

Earlier versions of this report were utilized in Chapter 10 of RAGS to help in the evaluation of risks posed by exposure to ionizing radiation. These more current recommendations should now be considered in evaluating risks to ionizing radiation.

2.17 Guidance for Data Usability in Risk Assessment.

U.S. Environmental Protection Agency. 1990. Office of Emergency and Remedial Response. Washington, D.C. EPA 540/G-90-OO8.

EPA has established a Data Useability Workgroup to develop national guidance for minimum data quality requirements to increase the usability of environmental analytical data in the cleanup of hazardous waste sites under CERCLA. This guidance manual provides direction for planning and assessing analytical data collection activities for the baseline human health risk assessment. ‘he manual provides guidance on the following specific topics:

- How to design remedial investigation sampling and analytical activities that meet the data quality and data quantity needs of risk assessors.
- Procedures for assessing the usability of the environmental analytical data obtained in the remedial investigation.
- Options for combining data of varying levels of quality from different sources and incorporating them into the risk assessment.
- Procedures for determining the degree of confidence in the risk assessment based on the uncertainty in the environmental analytical data.
- Guidelines for timing and execution of the various activities.
- Appendices requested by risk assessors and remedial project managers that describe data review summaries, assist in selecting analytical methods to meet required detection limits, and describe data qualifier flags.

2.18 Health Effects of Exposure to Low Levels of Ionizing Radiation (BEIR V).

National Academy of Sciences (NAS). 1990. National Academy Press. Washington, D. C.

This report is an update of the 1980 BEIR III report. Since that report there has been significant developments in the knowledge of the extent of radiation exposures from natural sources and medical uses as well as new data on the late health effects of radiation in humans, primarily the induction of cancer and developmental abnormalities. Advanced computational techniques and models for analysis have become available for radiation risk assessment. This report is divided into the following categories

- heritable genetic effects,
- cellular radiobiology and carcinogenic mechanisms,
- radiation carcinogenesis,

- radiation effects on the fetus, and
- radiation epidemiology and risk modeling.

This report also includes information and analyses from the BEIR IV report that are appropriate for cancer and genetic risk assessment. BEIR V is the current report that should be used for evaluating risks from low levels of ionizing radiation. Guidance for evaluation of risks from radiation can be found in Chapter 10 of Risk Assessment Guidance for Superfund.

2.19 Exposure Assessment Methods Handbook.

U.S. Environmental Protection Agency. 1991. Office of Health and Environmental Assessment. Washington, D. C.

This handbook provides a summary of the available algorithms and parameter values that can be used to determine estimated or modeled concentrations of chemicals in various environmental media, including ambient air, surface water, ground water, fish and shellfish, terrestrial food sources, and soil. Quantitative treatment of changes in concentration of chemicals due to environmental fate processes is provided for ambient air, surface water, and ground water. It also provides an overview of the exposure assessment process and how these methods are integrate d within that process. In addition, it presents discussions of methods for characterizing and enumerating exposed populations and of methods for quantitating the statistical uncertainties related to estimation of environmental concentrations.

2.20 Supplemental Guidance to Rags: Standard Default Exposure Factors.

U.S. Environmental Protection Agency. 1991. Office of Emergency and Remedial Response. Washington, D. C. OSWER Directive: 9285.6-03.

This supplemental guidance was published to reduce unwarranted variability in the exposure assumptions used to characterize potentially exposed populations in residential, commercial/industrial, agricultural, and recreational exposure scenarios. This guidance also addresses present and future land use considerations. If values differ between this guidance and RAGS, the values in this supplemental guidance supersede those in RAGS.

2.21 Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals).

U.S. *Environmental Protection Agency. 1991. Office of Emergency and Remedial Response. Washington D.C. PB92-963333.*

This guidance manual is based on policies in the Final Rule of the NCP which was published in 1990. Part B provides guidance on using EPA toxicity values and exposure information to derive chemical-specific, risk-based preliminary remedial goals (PRGs) for a CERCLA site. Chemical-specific PRGs are concentration goals for individual chemicals for specific medium and land-use combinations. PRGs provide remedial design staff with long-term targets to use during analysis and selection of remedial alternatives. PRGs are developed early in the RI/FS process before the baseline risk assessment is completed. Information from PRGs is not used in the baseline risk assessment although information from the RI will be used for both the BRA and the PRGs.

2.22 Risk Assessment Guidance for Superfund-Volume I: Human Health Evaluation Manual (Part C, Risk Evaluation of Remedial Alternatives).

U.S. *Environmental Protection Agency. 1991. Office of Emergency and Remedial Response. Washington, D. C. PB92-963334.*

This guidance has been developed by EPA to assist RPMs, risk assessors, site engineers, and others in using risk information at CERCLA sites to evaluate remedial alternatives during the FS and to evaluate the human health risk associated with the selected remedial alternative during and after its implementation. This Part provides general guidance to assist in site-specific risk evaluations. It discusses the statutes, regulations, and guidance relevant to the evaluation of remedial alternatives, describes appropriate levels of effort for risk evaluations of remedial alternative discusses the importance of risk communication, addresses the role of the RPM, and describes the need for documentation. PRGs developed using Part B of RAGS will help to evaluate the human risks of remedial alternatives

2.23 Guidelines for Developmental Toxicity Risk Assessment.

U.S. *Environmental Protection Agency. 1991. Office of Health and Environmental Assessment. Washington, D. C. 56 FR 63798.*

These guidelines outline principles and methods for evaluating data from animal and human studies, exposure data, and other information to characterize risk to human development growth, survival, and function because of exposure prior to conception, prenatally, or to infants and children. It adds new guidance on the relationship between maternal and developmental toxicity, characterization of the health-related data base for developmental toxicity. risk assessment, use of the reference dose or reference concentration for developmental toxicity (RfD_{DT} or RfC_{DT}), and use of the benchmark dose approach These guidelines replace the Guidelines for the Health Assessment of Suspect Developmental Toxicants. This is one of three guidelines issued for assessing non-cancer health effects. It is intended to be utilized for the non-cancer toxicity assessment component of the BRA outlined in RAGS.

2.24 Guidance for Risk Assessment - Henry Habicht Memorandum.

U.S. Environmental Protection Agency. 1991. Office of The Administrator. Washington, D.C. (February 26, 1992).

This guidance applies to the development evaluation, and description of EPA risk assessments for use in regulatory decision-making. Some of the principles outlined in this guidance describe information expected in EPA risk assessments to the extent practicable, emphasizing that discussion of both data and confidence in the data are essential features of a complete risk assessment. Guidance on exposure risk descriptors (i.e., central tendency, high end of individual risk, population risk and important subgroups) is also presented in this document. This is internal guidance that applies directly to assessments developed under EPA auspices. It also encourages EPA staff to use these principles as guidance in evaluating assessments submitted to EPA from other sources.

2.25 Dermal Exposure Assessment: Principles and Applications.

U.S. Environmental Protection Agency. 1992. Office of Research and Development. Washington, D.C. EPA 600/8-91/011B.

The dermal contact pathways specifically addressed are direct contact with soils, contact with contaminants in water, and contact with vapors. Priority was given to developing procedures oriented toward chronic systemic risks rather than acute local risks. This document:

- summarizes the current state of knowledge concerning dermal exposure to water, soil, and vapor media;

- presents methods for estimating dermal absorption resulting from contact with these media and elaborates upon their associated uncertainties;

- summarizes available chemical-specific experimental data describing the dermal absorption properties and provides predictive techniques to use where data are not available; and

- establishes a procedure for evaluating experimental data for application to exposure assessments.

This document is divided into two parts. Part 1 describes general principles of dermal absorption, while Part 2 presents methods for applying the principles described in Part 1 to human exposure assessments. This document provides valuable information for assessing dermal exposures, but it is an interim report, and therefore the models it addresses should be used with caution.

2.26 Supplemental Guidance to RAGS: Calculating the Concentration Term.

U.S. Environmental Protection Agency, 1992. Office of Solid Waste and Emergency Response. Washington, D.C. Publication 9285.7-081.

This supplemental guidance to RAGS is designed to help explain the concentration term in the reasonable maximum exposure (RME) equation. It presents the general RME equation, explains the significance of the RME, discuses basic concepts concerning the concentration term, describes generally how to calculate the concentration term, and presents examples to illustrate several important points.

2.27 Guidelines for Exposure Assessment.

U.S. Environmental Protection Agency. 1992. Office of Health and Environmental Assessment. Washington, D.C. 57 FR 22888.

These guidelines describe the general concepts of exposure assessment, including definitions and associated units, and provides guidance on planning and conducting an exposure assessment. Guidance is also provided on presenting the results of the exposure assessment and characterizing uncertainty. These guidelines supersede and replace the Guidelines for Estimating Exposures (USEPA, 1986a).

2.28 An SAB Report: Superfund Site Health Risk Assessment Guidelines; Review of the Office of Solid Waste and Emergency Response's Draft Risk Assessment Guidance for Superfund Human Health Evaluation Manual by the Environmental Health Committee.

U.S. Environmental Protection Agency. 1993. Office of the Administrator, Science Advisory Board. Washington, D.C. EPA-SAB-EHC-93-O07.

This report is a review of the EPA's Office of Solid Waste and Emergency Response (OSWER) risk assessment methodology. The Science Advisory Board reviewed four broad issue areas relating to Superfund human health risk assessment:

- defining and calculating the reasonable maximum exposure (RME);
- assessing and dealing with exposure to multiple chemicals--using the hazard index/hazard quotient to assess risk;
- reference doses in goal-setting--use of chronic/subchronic reference doses and specific populations to set risk-driven remediation goals; and
- short-term toxicity values--use of appropriate defaults for characterizing less-than-lifetime exposure to toxicants.

3.0 Toxicity Data Sources

3.1 Integrated Risk Information Service (IRIS).

U.S. Environmental Protection Agency. 1991.

IRIS provides numerical toxicity values, reference doses (RfDs), and cancer slope factors for various chemicals for use in Superfund risk assessments. IRIS is an EPA data base containing current health risk and EPA regulatory information for approximately 500 specific substance-s. It contains summaries of EPA qualitative and quantitative human health information that support two steps (hazard identification and dose response) of the four major steps of the risk assessment process outlined in the National Research Council's 1983 publication, Risk Assessment in the Federal Government: Managing the Process.

IRIS was created in 1986 for EPA staff as the official repository of consensus information regarding the areas of hazard identification and dose-response assessment. On June 2, 1988, a Federal Register notice (53 FR 21162) was issued to announce that IRIS was available to the public. The notice described IRIS, the type of information it contained, and how to access the system. It also informed the public about the IRIS Information Submission Desk, which provides an opportunity for public input- Data submission procedures are provided in the Federal Register notice (58 FR 11490) along with a list of the specific work group review schedules. Every six months, the data submission procedures will be reprinted in the Federal Register with a new or revised list or substances for work group review. For the latest status of the substances scheduled for review, interested persons should check the IRIS data base or contact:

IRIS User Support
U.S. Environmental Protection Agency
26 W. Martin Luther King Drive, (MS-190)
Cincinnati, Ohio 45268
Telephone: (513) 569-7254

The database information supporting risk characterization consists of brief statements on the quality of data and very general statements on confidence in the dose-response evaluation. IRIS consensus information does not include exposure assessment information. IRIS contains RfDs and slope factors that have been verified by the RfD or Carcinogen Risk Assessment Verification Endeavor (CRAVE) Workgroups and, subsequently, is considered to be the preferred source of toxicity information.

Information in IRIS supersedes all other sources. Only if information is not available in IRIS for the chemical being evaluated should other sources be consulted The data base contains three consensus health hazard information summary sections

- the reference dose for noncancer health effects resulting from oral exposure,
- the reference concentration for noncancer health effects resulting from inhalation exposure, and
- the carcinogen assessment for both oral and inhalation exposure.

IRIS substance files may include supplemental information such as summaries on health advisories, regulatory sections, and physical/chemical properties.

3.2 Health Effects Assessment Summary Tables (HEAST).

U.S. Environmental Protection Agency. 1994. Office of Emergency and Remedial Response. Washington D.C. OERR 9200.6-303 (92-1); NTIS No. PB92-921199.

The HEAST is a comprehensive listing consisting almost entirely of provisional risk assessment information relative to oral and inhalation routes for chemicals of interest to Superfund and RCRA. Entries in the HEAST are limited to chemicals that have undergone review and have the concurrence of individual EPA Program offices. The risk assessment information is not considered as high-quality, EPA-wide consensus information.

Chemicals reviewed by EPA Work Groups are classified according to their status as either verified, not verifiable, or under review. The toxicity values listed in HEAST (other than National Ambient Air Quality standards [NAAQS] or drinking water criteria values) are considered to be provisional. Provisional values are found in HEAST but not in IRIS. Verified numbers are found in both IRIS and HEAST. The HEAST are categorized into the following tables:

- HEAST Table 1: Subchronic and Chronic Toxicity (Other Than Carcinogenicity)
- HEAST Table 2: Alternate Methods-Subchronic and Chronic Toxicity
- HEAST Table 3: Carcinogenicity
- HEAST Table 4A and 4B: Radionuclide Carcinogenicity - Slope Factors

In 1992, HEAST Tables were modified to include: (1) the addition of Chemical Abstract Service Registry Number (CASRN) for each chemical, (2) the identification of the dose level, (3) the identification of target organs, and (4) a description of the critical effects. In addition, an Appendix (Appendix A) has also been developed with the following sections:

- data sources and selection criteria used in HEAST,
- RFD to RFC dose conversions,
- chemical name and CASRN reference,
- effect level definitions, and
- National Ambient Air Quality Standards (NAAQS).

APPENDIX B

Land Use in the CERCLA Remedy Selection Process

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 25 1995

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

OSWER Directive No. 9355.7-04

MEMORANDUM

SUBJECT: Land Use in the CERCLA Remedy Selection Process

FROM: Elliott P. Laws
Assistant Administrator

TO: Director, Waste Management Division
Regions I, IV, V, VII
Director, Emergency and Remedial Response Division
Region II
Director, Hazardous Waste Management Division
Regions III, VI, VIII, IX
Director, Hazardous Waste Division,
Region X
Director, Environmental Services Division
Regions I, VI, VII

Purpose:

This directive presents additional information for considering land use in making remedy selection decisions under the Comprehensive. Environmental Response, Compensation, and Liability Act (CERCLA) at National Priorities List (NPL) sites. The U.S. Environmental Protection Agency (EPA) believes that early community involvement, with a particular focus on the community's desired future uses of property associated with the CERCLA site, should result in a more democratic decisionmaking process; greater community support for remedies selected as a result of this process; and more expedited, cost-effective cleanups.

The major points of this directive are:

- Discussions with local land. use planning authorities, appropriate officials, and the public, as appropriate, should be conducted as early as possible in the scoping phase of the Remedial Investigation/Feasibility Study (RI/FS). This will assist EPA in understanding the reasonably anticipated future uses of the land on which the Superfund site is located;

- If the site is located in a community that is likely to have environmental justice concerns, extra efforts should be made to reach out to and consult with segments of the community that are not necessarily reached by conventional communication vehicles or through local officials and planning commissions;

- Remedial action objectives developed during the RI/FS should reflect the reasonably anticipated future land use or uses;

- Future land use assumptions allow the baseline risk assessment and the feasibility study to be focused on developing practicable and cost effective remedial alternatives. These alternatives should lead to site activities which are consistent with the reasonably anticipated future land use. However, there may be reasons to analyze implications associated with additional land uses;

- Land uses that will be available following completion of remedial action are determined as part of the remedy selection process. During this process, the goal of realizing reasonably anticipated future land uses is considered along with other factors. Any combination of unrestricted uses; restricted uses, or use for long-term waste management may result.

Discussions with local land use authorities and other locally affected parties to make assumptions about future land use are also appropriate in the RCRA context. EPA recognizes that RCRA facilities typically are industrial properties that are actively managed, rather than the abandoned sites that are often addressed under CERCLA. Therefore, consideration of non-residential uses is especially likely to be appropriate for RCRA facility cleanups. Decisions regarding future land use that are made as part of RCRA corrective actions raise particular issues for RCRA (e.g., timing, property transfers, and the viability of long-term permit or other controls) in ensuring protection of human health and the environment. EPA intends to address the issue of future land use as it relates specifically to RCRA facility cleanups in subsequent guidance and/or rulemakings.

This guidance is also relevant for Federal Facility sites. Land use assumptions at sites that are undergoing base closure may be different than at sites where a Federal agency will be maintaining control of the facility. Most land management agency sites will remain in Federal ownership after remedial actions. In these cases, Forest Land Management Plans and other resource management guidelines may help develop reasonable assumptions about future uses of the land. At all such sites, however., this document can focus the land use consideration toward appropriate options.[1]

Background:

Reasonably anticipated future use of the land at NPL sites is an important consideration in determining the appropriate extent of remediation. Future use of the land will affect the types of exposures and the frequency of exposures that may occur to any residual contamination remaining on the site, which in turn affects the nature of the remedy chosen. On the other hand, the alternatives selected through the National Oil and Hazardous Substance Contingency Plan (NCP) [55 Fed. Reg. 8666, March 8, 1990] process for CERCLA remedy selection determine the extent to which hazardous constituents remain at the site, and therefore affect subsequent available land and ground water uses.

The NCP preamble specifically discusses land use assumptions regarding the baseline risk assessment. The baseline risk assessment provides the basis for taking a remedial action at a Superfund site and supports the development of remedial action objectives . Land use assumptions affect the exposure pathways that are evaluated in the baseline risk assessment. Current land use is critical in determining whether there is a current risk associated with a Superfund site, and future land use is important in estimating potential future threats. The results of the risk assessment aid in determining the degree of remediation necessary to ensure long-term protection at NPL sites.

EPA has been criticized for too often assuming that future use will be residential. In many cases, residential use is the least restricted land use and where human activities are associated with the greatest potential for exposures. This directive is intended to facilitate future remedial decisions at NPL sites by outlining a public process and sources of information which should be considered in developing reasonable assumptions regarding future land use.

This directive expands on discussions provided in the preamble to the National Oil and Hazardous Substance Contingency Plan (NCP) ; “Risk Assessment Guidance for Superfund Vol. I, Human Health Evaluation Manual” (Part A) (EPA/540/l-89/002, Dec. 1989); “Guidance for Conducting Remedial Investigations and Feasibility studies Under CERCLA” (OSWER Directive 9355.3-01, Oct. 1988); and

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[1] Federal agency responsibility under CERCLA 120(h)(3), which relates to additional clean up which may be required to allow for unrestricted use of the property, is not addressed in this guidance.

"Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions" (OSWER Directive 9355.0-30, April 22, 1991).

This land use directive may have the most relevance in situations where surface soil is the primary exposure pathway. Generally, where soil contamination is impacting ground water, protection of the ground water may drive soil cleanup levels. Consideration of future ground water use for CERCLA sites is not addressed in this document. There are separate expectations established for ground water in the NCP rule section 300.430 (a) (1) (iii) (F) that "EPA expects to return usable ground waters to their beneficial uses wherever practicable, within a timeframe that is reasonable given the particular circumstances of the site."

Objective

This directive has two primary objectives. First, this directive promotes early discussions with local land use planning authorities, local officials, and the public regarding reasonably anticipated future uses of the property on which an NPL site is located. Second, this directive promotes the use of that information to formulate realistic assumptions regarding future land use and clarifies how these assumptions fit in and influence the baseline risk assessment, the development of alternatives, and the CERCLA remedy selection process.

Implementation

The approach in this guidance is meant to be considered at current and future sites in the RI/FS pipeline, to the extent possible. This directive is not intended to suggest that previous remedy selection decisions should be re-opened.

Developing Assumptions About Future Land Use

In order to ensure use of realistic assumptions regarding future land uses at a site, EPA should discuss reasonable anticipated future uses of the site with local land use planning authorities, local officials, and the public, as appropriate, as early as possible during the scoping phase of the RI/FS. EPA should gain an understanding of the reasonably anticipated future land uses at a particular Superfund site to perform the risk assessment and select the appropriate remedy.

A visual inspection of the site and its surrounding area is a good starting point in developing assumptions regarding future land use. Discussions with the local land use authorities and appropriate officials should follow. Discussions with the public can be accomplished through a public meeting and/or other means. By developing realistic assumptions based on information gathered from these sources early in the RI/FS process, EPA may develop remedial alternatives that are consistent with the anticipated future use.

The development of assumptions regarding the reasonably anticipated future land use should not become an extensive, independent research project. Site managers should use existing information to the extent possible, much of which will be available from local land use planning authorities. Sources and types of information that may aid EPA in determining the reasonably anticipated future land use include, but are not limited to:

- Current land use
- Zoning laws
- Zoning maps
- Comprehensive community master plans
- Population growth patterns and projections (e.g., Bureau of Census projections)
- Accessibility of site to existing infrastructure (e.g., transportation and public utilities)
- Institutional controls currently in place
- Site location in relation to urban, residential, commercial, industrial, agricultural and recreational areas
- Federal/State land use designation (Federal/State control over designated lands range from established uses for the general public, such as national parks or State recreational areas, to governmental . facilities providing extensive site access restrictions, such as Department of Defense facilities
- Historical or recent development patterns
- Cultural factors (e.g., historical sites, Native American religious sites)
- Natural resources information
- Potential vulnerability of ground water to contaminants that might migrate from soil
- Environmental justice issues
- Location of on-site or nearby wetlands
- Proximity of site to a floodplain
- Proximity of site to critical habitats of endangered or threatened species
- Geographic and geologic information
- Location of Wellhead Protection areas, recharge areas, and other areas identified in a State's Comprehensive Ground-water Protection Program

These types of information should be considered when developing the assumptions about future land use. Interaction with the public, which includes all stakeholders affected by the site, should serve to increase the certainty in the assumptions made regarding future land use at an NPL site and increase the confidence expectations about anticipated future land use are, in fact, reasonable.

For example, future industrial land use is likely to be a reasonable assumption where a site is currently used for industrial purposes, is located in an area where the surroundings are zoned for industrial use, and the comprehensive plan predicts the site will continue to be used for industrial purposes.

Community Involvement

NPL sites are located in diverse areas of the country, with great variability in land use planning practices. For some NPL sites, the future land use of a site may have been carefully considered through local, public, participatory, planning processes, such as zoning hearings, master plan approvals or other vehicles. When this is the case, local residents around the Superfund site are likely to demonstrate substantial agreement with the local land use planning authority on the future use of the property. Where there is substantial agreement among local residents and land use planning agencies, owners and developers, EPA can rely with a great deal of certainty. on the future land use already anticipated for the site. For other NPL sites, however, the absence or nature of a local planning process may yield considerably less certainty about what assumptions regarding future use are reasonable. In some instances the local residents near the Superfund site may feel disenfranchised from the local land use planning and development process. This may be an especially important issue where there are concerns regarding environmental justice in the neighborhood around the NPL site. Consistent with the principle of fairness, EPA should make an extra effort to reach out to the local community to establish appropriate future land use assumptions at such sites.

Land Use Assumptions in the Baseline Risk Assessment

Future land use assumptions allow the baseline risk assessment and the feasibility study to focus on the development of practicable and cost-effective remedial alternatives, leading to site activities which are consistent with the reasonable anticipated future land use.

The baseline risk assessment generally needs only to consider the reasonably anticipated future land use; however, it may be valuable to evaluate risks associated with other land uses. The NCP preamble (55 Fed. Reg. 8710) states that in the baseline risk assessment, more than one future land use assumption may be considered when decision makers wish to understand the implications of unexpected exposures. Especially where there is some uncertainty regarding the anticipated future land use, it may be useful to compare the potential risks associated with several land use scenarios to estimate the impact on human health and the environment should the land use unexpectedly change. The magnitude of such potential impacts may be an important consideration in determining whether and how institutional controls should be used to restrict future uses. If the baseline risk assessment evaluates a future use under which exposure is limited, it will not serve the traditional role, evaluating a "no action" scenario. A remedy, i.e. institutional controls to limit future exposure, will be required to protect human health and the environment. In addition to analyzing human health exposure scenarios associated with certain land uses, ecological exposures may also need to be considered.

Developing Remedial Action Objectives

Remedial action objectives provide the foundation upon which remedial cleanup alternatives are developed. In general, remedial action objectives should be developed in order to develop alternatives that would achieve cleanup levels associated with the reasonable anticipated future land use over as much of the site as possible. EPA recognizes, however, that achieving either the reasonably anticipated land use, or the land use preferred by the community, may not be practicable across the entire site, or in some cases, at all. For example, as RI/FS data become available, they may indicate that the remedial alternatives under consideration for achieving a level of cleanup consistent with the reasonably anticipated future land use are not cost-effective nor practicable. If this is the case, the remedial action objective may be revised which may result in different, more reasonable land use(s).

EPA's remedy selection expectations described in section 300.430(a)(1)(iii) of the NCP should also be considered, when developing remedial action objectives. Where practicable, EPA expects to treat principal threats, to use engineering controls such as containment for low-level threats, to use institutional controls to supplement engineering controls, to consider the use of innovative technology, and to return usable ground waters to beneficial uses to protect human health and the environment. (Some types of applicable or relevant and appropriate requirements (ARARs) define protective cleanup levels which may, in turn, influence post-remediation land use potential.)

In cases where the future land use is relatively certain, the remedial action objective generally should reflect this land use. Generally, it need not include alternative land use scenarios unless, as discussed above, it is impracticable to provide a protective remedy that allows for that use. A landfill site is an example where it is highly likely that the future land use will remain unchanged (i.e., long-term waste management area) , given the NCP's expectation that treatment of high volumes of waste generally will be impracticable and the fact that EPA's presumptive remedy for landfills is containment. In such a case, a remedial action objective could be established with a very high degree of certainty to reflect the reasonably anticipated future land use.

In cases where the reasonably anticipated future land use is highly uncertain, a range of the reasonably likely future land uses should be considered in developing remedial action objectives. These likely future land uses can be reflected by developing a range of remedial alternatives that will achieve different land use potentials. The remedy selection process will determine which alternative is most appropriate for the site and, consequently, the land use(s) available following remediation.

As discussed in "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions" (OSWER Directive 9355.0-30, April 22, 1991), EPA has established a risk range for carcinogens within which EPA strives to manage site risks. EPA recognizes that a specific cleanup level within the acceptable risk range may be associated with more than one land use (e.g., an industrial cleanup to 10^{-6} may also allow for residential use at a 10^{-4} risk level.) It is not EPA's intent that the risk range be partitioned into risk standards based solely on categories of land use (e.g., with residential cleanups at the 10-6 level and industrial cleanups at the 10^{-4} risk level.) Rather, the risk range provides the necessary flexibility to address the technical and cost limitations, and the performance and risk uncertainties inherent in all waste remediation efforts.

Land Use Considerations in Remedy Selection

As a result of the comparative analysis of alternatives with respect to EPA's nine evaluation criteria, EPA selects a site-specific remedy. The remedy determines the cleanup levels, the volume of contaminated material to be treated, and the volume of contaminated material to be contained. Consequently, the remedy selection decision determines the size of the area that can be returned to productive use and the particular types of uses that will be possible following remediation.

The volume and concentration of contaminants left on-site, and thus the degree of residual risk at a site, will affect future land use. For example, a remedial alternative may include leaving in place contaminants in soil at concentrations protective for industrial exposures, but not protective for residential exposures. In this case, institutional controls should be used to ensure that industrial use of the land is maintained and to prevent risks from residential exposures. Conversely, a remedial alternative may result in no waste left in place and allow for unrestricted use (e.g., residential use) .

Results of Remedy Selection Process

Several potential land use situations could result from EPA's remedy selection decision. They are:

- The remedy achieves cleanup levels that allow the entire site to be available for the reasonably anticipated future land use in the baseline risk assessment (or, where future land use is uncertain, all uses that could reasonably be anticipated).

- The remedy achieves cleanup levels that allow most, but not all, of the site to be available for the reasonably anticipated future land use. For example, in order to be cost effective and practicable, the remedy may require creation of a long-term waste management area for containment of treatment residuals or low-level waste on a small portion of the site. The cleanup levels in this portion of the site might allow for a more restricted land use.

- The remedy achieves cleanup levels that require a more restricted land use than the reasonably anticipated future land use for the entire site. This situation occurs when no remedial alternative that is cost-effective or practicable will achieve the cleanup levels consistent with the reasonably anticipated future land use. The site may still be used for productive purposes. but the use would be more restricted than the reasonably anticipated future land use. Furthermore, the more restricted use could be a long-term waste management area over all or a portion of the site.

Institutional Controls

If any remedial alternative developed during the FS will require a restricted land use in order to be protective, it is essential that the alternative include components that will ensure that it remain protective. In particular, institutional controls will generally have to be included in the alternative to prevent an unanticipated change in land use that could result in unacceptable exposures to residual contamination, or, at a minimum, alert future users to the residual risks and monitor for any changes in use. In such cases, institutional controls will play a key role in ensuring long-term protectiveness and should be evaluated and implemented with the same degree of care as is given to other elements of the remedy. In developing remedial alternatives that include institutional controls, EPA should determine: the type of institutional control to be used, the existence of the authority to implement the institutional control, and the appropriate entity's resolve and ability to implement the institutional control. An alternative may anticipate two or more options for establishing institutional controls, but should fully evaluate all such options. A variety of institutional controls may be used such as deed restrictions and deed notices, and adoption of land use controls by a local government. These controls either prohibit certain kinds of site - uses or, at a minimum, notify potential owners or land users of the presence of hazardous substances remaining on site at levels that are not protective for all uses. Where exposure must be limited to assure protectiveness, a deed notice alone generally will not provide a sufficiently protective remedy. While the ROD need not always specify the precise type of control to be imposed, sufficient analysis should be shown in the FS and ROD to support a conclusion that effective implementation of institutional controls can reasonably be expected.

Suppose, for example, that a selected remedy will be protective for industrial land use and low levels of hazardous substances will remain on site. An industry still may be able to operate its business with the selected remedy in place. Institutional controls, however, generally will need to be established to ensure the land is not used for other, less restricted purposes, such as residential use, or to alert potential buyers of any remaining contamination.

Future Changes in Land Use

Where waste is left on-site at levels that would require limited use and restricted exposure, EPA will conduct reviews at least every five years to monitor the site for any changes. Such reviews should analyze the implementation and effectiveness of institutional controls with the same degree of care as other parts of the remedy. Should land use change, it will be necessary to evaluate the implications of that change for the selected remedy, and whether the remedy remains protective. EPA's role in any subsequent additional cleanup will be determined on a site-specific basis. If landowners or others decide at a future date to change the land use in such a way that makes further cleanup necessary to ensure protectiveness, CERCLA does not prevent them from conducting such a cleanup as long as protectiveness of the remedy is not compromised. (EPA may invoke CERCLA section 122(e)(6), if necessary, to prevent actions that are inconsistent with the original remedy.) In general, EPA would not expect to become involved. actively in the conduct or oversight of such cleanups. EPA, however, retains its authority to take further response action where necessary to ensure protectiveness.

Further Information

If you have any questions concerning this directive, please call Sherri Clark at 703-603-9043.

NOTICE : The policies set out in this memorandum are intended solely as guidance. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this memorandum, or to act at variance with the guidance, based on an analysis of specific site circumstances. Remedy selection decisions are made and justified on a case-specific basis. The Agency also reserves the right to change this guidance at any time without public notice.

APPENDIX C

EPA Risk Characterization Program

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20450

THE ADMINISTRATOR

MAR 2 1 1995

MEMORANDUM

SUBJECT: EPA Risk Characterization Program

TO: Assistant Administrators
Associate Administrators
Regional Administrators
General Counsel
Inspector General

EPA has achieved significant pollution reduction over the past 20 years, but the challenges we face now are very different from those of the past. Many more people are aware of environmental issues today than in the past and their level of sophistication and interest in understanding these issues continues to increase. We now work with a populace which is not only interested in knowing what EPA thinks about a particular issue, but also how we come to our conclusions.

More and more key stakeholders in environmental issues want enough information to allow them to independently assess and make judgments about the significance of environmental risks and the reasonableness of our risk reduction actions. If we are to succeed and build our credibility and stature as a leader in environmental protection for the next century, EPA must be responsive and resolve to more openly and fully communicate to the public the complexities and challenges of environmental decisionmaking in the face of scientific uncertainty.

As the issues we face become more complex, people both inside and outside of EPA must better understand the basis for our decisions, as well as our confidence in the data, the science policy judgments we have made, and the uncertainty in the information base. In order to achieve this better understanding, we must improve the way in which we characterize and communicate environmental risk. We must embrace certain fundamental values so that we may begin the process of changing the way in which we interact With each other, the public, and key stakeholders on environmental risk issues. I need your help to ensure that these values are embraced and that we change the way we do business.

First, we must adopt as values **transparency** in our decisionmaking process and **clarity in** communication with each other and the public regarding environmental risk and the uncertainties associated with our assessments of environmental risk. This means that we must My, openly, and clearly characterize risks. In doing so, we will disclose the scientific analyses, uncertainties, assumptions, and science policies which underlie our decisions as they are made throughout the risk assessment and risk management processes. I want to be sure that key science policy issues are identified as such during the risk assessment process, that policymakers are fully aware and engaged in the selection of science policy options, and that their choices and the rationale for those choices are clearly articulated and visible in our communications about environmental risk.

I understand that some maybe concerned about additional challenges and disputes. I expect that we will see more challenges, particularly at first. However, I strongly believe that making this change to a more open decisionmaking process will lead to more meaningful public . participation, better information for decisionmaking improved decisions, and more public support and respect for EPA positions and decisions. There is value in sharing with others the complexities and challenges we face in making decisions in the face of uncertainty. I view making this change as essential to the long term success of this Agency.

Clarity in communication also means that we will strive to help the public put environmental risk in the proper perspective when we take risk management actions. We must meet this challenge and find legitimate ways to help the public better comprehend the relative significance of environmental risks.

Second, because **transparency** in decisionmaking and **clarity** in communication will likely lead to more outside questioning of our assumptions and science policies, we must be more vigilant about ensuring that our core assumptions and science policies are consistent and comparable across programs, well grounded in science, and that they fall within a “zone of reasonableness.”

While I believe that the American public expects us to err on the side of protection in the face of scientific uncertainty, I do not want our assessments to be unrealistically conservative. We cannot lead the fight for environmental protection into the next century unless we use common sense in all we do.

These core values of transparency, clarity, consistency, and reasonableness need to guide each of us in our day-to-day work; from the toxicologist reviewing the individual cancer study, to the exposure and risk assessors, to the risk manager, and through to the ultimate decisionmaker. I recognize that issuing this memo will not by itself result in any change. You need to believe in the importance of this change and convey your beliefs to your managers and staff through your words and actions in order for the change to occur. You also need to play an integral role in developing the implementing policies and procedures for your programs.

I am issuing the attached EPA Risk Characterization Policy and Guidance today. I view these documents as building blocks for the development of your program-specific policies and procedures. The Science Policy Council (SPC) plans to adopt the same basic approach to implementation as was used for Peer Review. That is, the Council will form an Advisory Group that will work with a broad Implementation Team made up of representatives from every Program Office and Region. Each Program Office and each Region will be asked by the Advisory Group to develop program and region-specific policies and procedures for risk characterization consistent with the values of **transparency, clarity, consistency, and reasonableness** and consistent with the attached policy and guidance.

I recognize that as you develop your Program-specific policies and procedures you are likely to need additional tools to fully implement this policy. I want you to identify these needed tools and work cooperatively with the Science Policy Council in their development. I want your draft program and region-specific policies, procedures, and implementation plans to be developed and submitted to the Advisory Group for review by no later than May 30, 1995. You will be contacted shortly by the SPC Steering Committee to obtain the names of your nominees to the implementation Team.

Carol M. Browner

Attachments

March 1995

POLICY FOR RISK CHARACTERIZATION

at the U.S. Environmental Protection Agency

INTRODUCTION

Many EPA policy decisions are based in part on the results of risk assessment, an analysis of scientific information on existing and projected risks to human health and the environment. As practiced at EPA, risk assessment makes use of many different kinds of scientific concepts and data (e.g., exposure, toxicity, epidemiology, ecology), all of which are used to "characterize" the expected risk associated with a particular agent or action in a particular environmental context. Informed use of reliable scientific information from many different sources is a central feature of the risk assessment process.

Reliable information may or may not be available for many aspects of a risk assessment. Scientific uncertainty is a fact of life for the risk assessment process, and agency managers almost always must make decisions using assessments that are not as definitive in all important areas as would be desirable. They therefore need to understand the strengths and the limitations of each assessment, and to communicate this information to all participants and the public.

This policy reaffirms the principles and guidance found in the Agency's 1992 policy (Guidance on Risk Characterization for Risk Managers and Risk Assessors, February 26, 1992). That guidance was based on EPA's risk assessment guidelines, which are products of peer review and public comment. The 1994 National Research Council (NRC) report, "Science and Judgment in Risk Assessment," addressed the Agency's approach to risk assessment, including the 1992 risk characterization policy. The NRC statement accompanying the report stated, "... EPA's overall approach to assessing risks is fundamentally sound despite often-heard criticisms, but the Agency must more clearly establish the scientific and policy basis for risk estimates and better describe the uncertainties in its estimates of risk."

This policy statement and associated guidance for risk characterization is designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk and that this information is communicated from risk assessors to risk managers (policy makers), from middle to upper management, and from the Agency to the public. Additionally, the policy will provide a basis for greater clarity, transparency, reasonableness, and consistency in risk assessments across Agency programs. While most of the discussion and examples in this policy are drawn from health risk assessment, these values also apply to ecological risk assessment. A parallel effort by the Risk Assessment Forum to develop EPA ecological risk assessment guidelines will include guidance specific to ecological risk characterization.

Policy Statement

Each risk assessment prepared in support of decision-making at EPA should include a risk characterization that follows the principles and reflects the values outlined in this policy. A risk characterization should be prepared in a manner that is clear, transparent, reasonable and consistent with other risk characterizations of similar scope prepared across programs in the Agency. Further, discussion of risk in all EPA reports, presentations, decision packages, and other documents should be substantively consistent with the risk characterization. The nature of the risk characterization will depend upon the information available, the regulatory application of the risk information, and the resources (including time) available. In all cases, however, the assessment should identify and discuss all the major issues associated with determining the nature and extent of the risk and provide commentary on any constraints limiting fuller exposition.

Key Aspects of Risk Characterization

Bridging risk assessment and risk management. As the interface between risk assessment and risk management, risk characterizations should be clearly presented, and separate from any risk management considerations. Risk management options should be developed using the risk characterization and should be based on consideration of all relevant factors, scientific and nonscientific.

Discussing confidence and uncertainties. Key scientific concepts, data and methods (e.g., use of animal or human data for extrapolating from high to low doses, use of pharmacokinetics data, exposure pathways, sampling methods, availability of chemical-specific information, quality of data) should be discussed. To ensure transparency, risk characterizations should include a statement of confidence in the assessment that identifies all major uncertainties along with comment on their influence on the assessment, consistent with the Guidance on Risk Characterization (attached).

Presenting several types of risk information. Information should be presented on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (e.g., central tendency, high end of individual risk, population risk, important subgroups, if known) consistent with terminology in the Guidance on Risk Characterization, Agency risk assessment guidelines, and program-specific guidance. In decisionmaking, risk managers should use risk information appropriate to their program legislation.

EPA conducts many types of risk assessments, including screening-level assessments of new chemicals, in-depth assessments of pollutants such as dioxin and environmental tobacco smoke, and site-specific assessments for hazardous waste sites. An iterative approach to risk assessment, beginning with screening techniques, may be used to determine if a more comprehensive assessment is necessary. The degree to which confidence and uncertainty are addressed in a risk characterization depends largely on the scope of the assessment. In general, the scope of the risk characterization should reflect the information presented in the risk assessment and program-specific guidance. When special circumstances (e.g., lack of data, extremely complex situations, resource limitations, statutory deadlines) preclude a full assessment, such circumstances should be explained and their impact on the risk assessment discussed.

Risk Characterization in Context

Risk assessment is based on a series of questions that the assessor asks about scientific information that is relevant to human and/or environmental risk. Each question calls for analysis anti interpretation of the available studies, selection of the concepts and data that are most scientifically reliable and most relevant to the problem at hand, and scientific conclusions regarding the question presented. For example, health risk assessments involve the following questions:

Hazard Identification - What is known about the capacity of an environmental agent for causing cancer or other adverse health effects in humans, laboratory animals, or wildlife species? What are the related uncertainties and science policy choices?

Dose Response Assessment - What is known about the biological mechanisms and dose-response relationships underling any effects observed in the laboratory or epidemiology studies providing data for the assessment? What are the related uncertainties and science policy choices?

Exposure Assessment - What is known about the principal paths, patterns, and magnitudes of human or wildlife exposure and numbers of persons or wildlife species likely to be exposed? What are the related uncertainties and science policy choices?

Corresponding principles and questions for ecological risk assessment are being discussed as part of the effort to develop ecological risk guidelines.

Risk characterization is the summarizing step of risk assessment. The risk characterization integrates information from the preceding components of the risk assessment and synthesizes an overall conclusion about risk that is complete, informative and useful for decisionmakers.

Risk characterizations should clearly highlight both the confidence and the uncertainty associated with the risk assessment. For example, numerical risk estimates should always be accompanied by descriptive information carefully selected to ensure an objective and balanced characterization of risk in risk assessment reports and regulatory documents. In essence, a risk characterization conveys the assessor's judgment as to the nature and existence of (or lack of) human health or ecological risks. Even though a risk characterization describes limitations in an assessment, a balanced discussion of reasonable conclusions and related uncertainties enhances, rather than detracts, from the overall credibility of each assessment.

"Risk characterization" is not synonymous with "risk communication." This risk characterization policy addresses the interface between risk assessment and risk management. Risk communication, in contrast, emphasizes the process of exchanging information and opinion with the public - including individuals, groups, and other institutions. The development of a risk assessment may involve risk communication. For example, in the case of site-specific assessments for hazardous waste sites, discussions with the public may influence the exposure pathways included in the risk assessment. While the final risk assessment document (including the risk characterization) is available to the public, the risk communication process may be better served by separate risk information documents designed for particular audiences.

Promoting Clarity, Comparability and Consistency

There are several reasons that the Agency should strive for greater clarity, consistence and comparability in risk assessments. One reason is to minimize confusion. For example, many people have not understood that a risk estimate of one in a million for an "average" individual is not comparable to another one in a million risk estimate for the "most exposed individual." Use of such apparently similar estimates without further explanation leads to misunderstandings about the relative significance of risks and the protectiveness of risk reduction actions.

EPA's Exposure Assessment Guidelines provide standard descriptors of exposure and risk. Use of these terms in all Agency risk assessments will promote consistency and comparability. Use of several descriptors, rather than a single descriptor, will enable EPA to present a fuller picture of risk that corresponds to the range of different exposure conditions encountered by various individuals and population exposed to most environmental chemicals.

Legal Effect

This policy statement and associated guidance on risk characterization do not establish or affect legal rights or obligations. Rather, they confirm the importance of risk characterization as a component of risk assessment, outline relevant principles, and identify factors Agency staff should consider in implementing the policy.

The policy and associated guidance do not stand alone; nor do they establish a binding norm that is finally determinative of the issues addressed. Except where otherwise provided by law, the Agency's decision on conducting a risk assessment in any particular case is within the Agency's discretion. Variations in the application of the policy and associated guidance, therefore, are not a legitimate basis for delaying or complicating action on Agency decisions.

Applicability

Except where otherwise provided by law and subject to the limitations on the policy's legal effect discussed above, this policy applies to risk assessments prepared by EPA and to risk assessments prepared by others that are used in support of EPA decisions.

EPA will consider the principles in this policy in evaluating assessments submitted to EPA to complement or challenge Agency assessments. Adherence to this Agency-wide policy will improve understanding of Agency risk assessments, lead to more informed decisions, and heighten the credibility of both assessments and decisions.

Implementation

Assistant Administrators and Regional Administrators are responsible for implementation of this policy within their organizational units. The Science Policy Council (SPC) is organizing Agency-wide implementation activities. Its responsibilities include promoting consistent interpretation, assessing Agency-wide progress, working with external groups on risk characterization issues and methods, and developing recommendations for revisions of the policy and guidance, as necessary.

Each Program and Regional office will develop office-specific policies and procedures for risk characterization that are consistent with this policy and the associated guidance. Each Program and Regional office will designate a risk manager or risk assessor as the office representative to the Agency-wide Implementation Team, which will coordinate development of office-specific policies and procedures and other implementation activities. The SPC will also designate a small cross-Agency Advisory Group that will serve as the liaison between the SPC and the Implementation Team.

In ensuring coordination and consistency among EPA offices, the Implementation Team will take into account statutory and court deadlines, resource i.replications, and existing Agency and program-specific guidance on risk assessment. The group will work closely with staff throughout Headquarters and Regional offices to promote development of risk characterizations that present a full and complete picture of risk that meets the needs of the risk managers.

APPROVED: ______________________ DATE: MAR 21 1995

Carol M. Browner, Administrator

ELEMENTS TO CONSIDER WHEN DRAFTING EPA RISK CHARACTERIZATIONS

March 1995

Background -- Risk Characterization Principles

There are a number of principles which form the basis for a risk characterization:

- Risk assessments should be transparent, in that the conclusions drawn from the science are identified separately from policy judgments, and the use of default values or methods and the use of assumption.s in the risk assessment are clearly articulated.

- Risk characterizations should include a summary of the key issues and conclusions of each of the other components of the risk assessment, as well as describe the likelihood of harm. The summary should include a description of the overall strengths and the limitations (including uncertainties) of the assessment and conclusions.

- Risk characterizations should be consistent in general format, but recognize the unique characteristics of each specific situation.

- Risk characterizations should include, at least in a qualitative sense, a discussion of how a specific risk and its context compares with other similar risks. This may be accomplished by comparisons with other chemicals or situations in which the Agency has decided to act, or with other situations which the public may be familiar with. The discussion should highlight the limitations of such comparisons.

- Risk characterization is a key component of risk communication, which is an interactive process involving exchange of information and export opinion among individuals, groups and institutions.

Conceptual Guide for Developing Chemical-Specific Risk Characterizations

The following outline is a guide and formatting aid for developing risk characterizations for chemical risk assessments. Similar outlines will be developed for other types of risk characterizations, including site-specific assessments and ecological risk assessments. A common format will assist risk managers in evaluating and using risk characterization.

The outline has two parts. The first part tracks the risk assessment to bring forward its major conclusions. The second part draws all of the information together to characterize risk. The outline represents the expected findings for a typical complete chemical assessment for a single chemical. However, exceptions for the circumstances of individual assessments exist and should be explained as part of the risk characterization. For example, particular statutory requirements, court-ordered deadlines, resource limitations, and other specific factors may be described to explain why certain elements are incomplete.

This outline does not establish or affect legal rights or obligations. Rather, it confirms the importance of risk characterization, outlines relevant principles, and identifies factors Agency staff should consider in implementing the policy. On a continuing basis, Agency' management is expected to evaluate the policy as well as the results of its application throughout the Agency and undertake revisions as necessary. Therefore, the policy does not stand alone; nor does it establish a binding norm that is finally determinative of the issues addressed. Minor variations in its application from one instance to another are appropriate and expected; they thus are not a legitimate basis for delaying or complicating action on otherwise satisfactory scientific, technical, and regulatory products.

PART ONE

SUMMARIZING MAJOR CONCLUSIONS IN RISK CHARACTERIZATION

I. Characterization of Hazard Identification

A. What "is the key toxicological study (or studies) that provides the basis for health concerns?
   – How good is the key study?
   – Are the data from laboratory or field studies? In single species or multiple species?
   – If the hazard is carcinogenic, comment on issues such as: observation of single or multiple tumor sites; occurrence of benign or malignant tumors; certain tumor types not linked to carcinogenicity; use of the maximum tolerated dose (MTD).
   – If the hazard is other than carcinogenic, what endpoints were observed, and what is the basis for the critical effect?
   – Describe other studies that support this finding.
   – Discuss any valid studies which conflict with this finding.

B. Besides the health effect observed in the key study, are there other health endpoints of concern?
   – What are the significant data gaps?

C. Discuss available epidemiological or clinical data. For epidemiological studies:
   – What types of studies were used, i.e., ecologic, case-control, cohort?

– Describe the degree to which exposures were adequately described.
– Describe the degree to which confounding factors were adequately accounted for.
– Describe the degree to which other causal factors were excluded.

D. How much is known about how (through what biological mechanism) the chemical produces adverse effects?
– Discuss relevant studies of mechanisms of action or metabolism.
– Does this information aid in the interpretation of the toxicity data?
– What are the implications for potential health effects?

E. Comment on any non-positive data in animals or people, and whether these data were considered in the hazard identification.

F. If adverse health affects have been observed in wildlife species, characterize such effects by discussing the relevant issues as in A through E above.

G. Summarize the hazard identification and discuss the significance of each of the following:
– confidence in conclusions;
– alternative conclusions that are also supported by the data; significant data gaps; and
– highlights of major assumptions.

II. Characterization of Dose-Response

A. What data were used to develop the dose-response curve? Would the result have been significantly different if based on a different data set?
- If animal data were used:
  – which species were used? most sensitive, average of all species, or other?
  – were any studies excluded? why?
- If epidemiological data were used:
  – Which studies were used? only positive studies, all studies, or some other combination?
  – Were any studies excluded? why?
  – Was a meta-analysis performed to combine the epidemiological studies? what approach was used? were studies excluded? why?

B. What model was used to develop the dose-response curve? What rationale supports this choice? Is chemical-specific information available to support this approach?
– For non-carcinogenic hazards:
  – How was the RfD/RfC (or the acceptable range) calculated?

– What assumptions or uncertainty factors were used?
– What is the confidence in the estimates?

– For carcinogenic hazards:
- – What dose-response model was used? LMS or other linear-at-low-dose model, a biologically-based model based on metabolism data, or data about possible mechanisms of action?
- – What is the basis for the selection of the particular dose-response model used? Are there other models that could have been used with equal plausibility and scientific validity? What is the basis for selection of the model used in this instance?

C. Discuss the route and level of exposure observed, as compared to expected human exposures.
- – Are the available data from the same route of exposure as the expected human exposures? If not, are pharmacokinetic data available to extrapolate across route of exposure?
- – How far does one need to extrapolate from the observed data to environmental exposures (one to two orders of magnitude? multiple orders of magnitude)? What is the impact of such an extrapolation?

D. If adverse health affects have been observed in wildlife species, characterize dose-response information using the process outlined in A-C.

III. Characterization of Exposure

A. What are the most significant sources of environmental exposure?
- – Are there data on sources of exposure from different media? What is the relative contribution of different sources of exposure?
- – What are the most significant environmental pathways for exposure?

B. Describe the populations that were assessed, including as the general population, highly exposed groups, and highly susceptible groups.

C. Describe the basis for the exposure assessment, including any monitoring, modeling, or other analyses of exposure distributions such as Monte-Carlo or krieging.

D. What are the key descriptors of exposure?
- – Describe the (range of) exposures to: “average” individual “high end” individuals, general population, high exposure group(s), children, susceptible populations.
- – How was the central tendency estimate developed? What factors and / or methods were used in developing this estimate?
- – How was the high-end estimate developed?

– Is there information on highly-exposed subgroups? Who are they?
– What are their levels of exposure? How are they accounted for in the assessment?

E. Is there reason to be concerned about cumulative or multiple exposures because of ethnic, racial, or socioeconomic reasons?

F. If adverse health affects have been observed in wildlife species, characterize wildlife exposure by discussing the relevant issues as in A through E above.

G. Summarize exposure conclusions and discuss the following
– results of different approaches, i.e. modeling, monitoring, probability distributions;
– limitations of each, and the range of most reasonable values; and
– confidence in the results obtained, and the limitations to the results.

PART TWO
RISK CONCLUSIONS AND COMPARISONS

IV. Risk Conclusions

A. What is the overall picture of risk, based on the hazard identification, dose-response and exposure characterizations?

B. What are the major conclusions and strengths of the assessment in each of the three main analyses (i.e., hazard identification, dose-response, and exposure assessment)?

C. What are the major limitations and uncertainties in the three main analyses?

D. What are the science policy options in each of the three major analyses?
– What are the alternative approaches evaluated?
– What are the reasons for the choices made?

V. Risk Context

A. What are the qualitative characteristics of the hazard (e.g., voluntary vs. involuntary, technological vs. natural, etc.)? Comment on findings, if any, from studies of risk perception that relate to this hazard or similar hazards.

B. What are the alternatives to this hazard? How do the risks compare?

C. How does this risk compare to other risks?

1. How does this risk compare to other risks in this regulatory program, or other similar risks that the EPA has made decisions about?
2. Where appropriate, can this risk be compared with past Agency decisions, decisions by other federal or state agencies, or common risks with which people may be familiar?
3. Describe the limitations of making these comparisons.

D. Comment on significant community concerns which influence public perception of risk?

VI. Existing Risk Information

Comment on other risk assessments that have been done on this chemical by EPA, ether federal agencies, or other organizations. Are there significantly different conclusions that merit discussion?

VII. Other Information

Is there other information that would be useful to the risk manager or the public in this situation that has not been described above?

March 1995

IMPLEMENTATION PROGRAM FOR THE EPA POLICY ON RISK CHARACTERIZATION

Introduction

The EPA Science Policy Council (SPC) is implementing the Administrator's policy on risk characterization through a year-long program of activities that will involve risk assessors and risk managers in the practice of fully characterizing risk. This interactive approach calls for inter- and intra-office activities to gain experience with the fundamentals of the policy and to resolve issues that were identified during Agency-wide review of early drafts. Implementation will include program-specific guidance development: case study development: and risk characterization workshops and roundtables for risk assessors and managers.

A SPC-sponsored "advisory group" will plan and execute these implementation activities. This advisory group will organize an "implementation team" composed of representatives from the program offices. regions and ORD laboratories and centers. This team will work closely with the advisory group to coordinate implementation activities" within their offices.

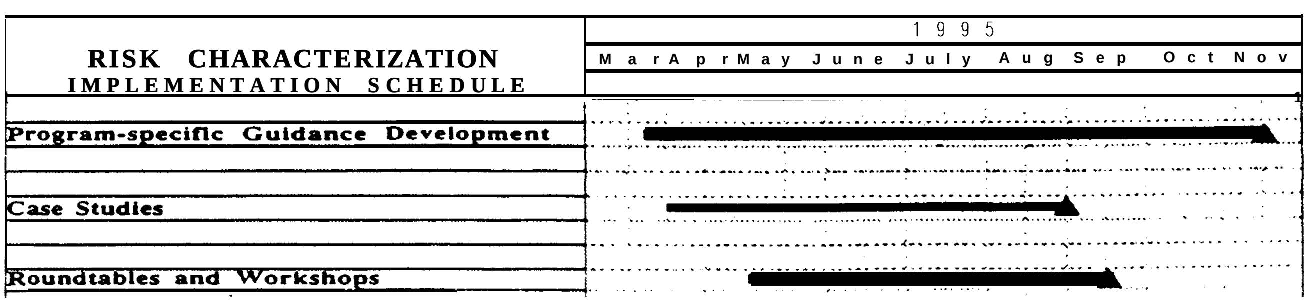
Program Guidance Development

Risk characterizations often differ according to the type of assessment involved. The aim is to work closely with the Program Offices and Regions to identify and address their specific risk characterization needs and. where appropriate, to develop assessment-specific guidance.

This program updates and implements the risk characterization guidance issued in early 1992. The policy features a paper entitled "Elements to Consider When Drafting EPA Risk Characterizations. " This paper outlines generic elements for characterizing risk, and provides a prototype for assessment-specific guidance. Program and Regional offices will use this paper to identify and address risk characterization issues associated with specific assessment types that differ from the general prototype (e.g., site-specific and ecological risk assessments). Lessons learned from the case studies. roundtables and workshops (discussed below) will also contribute to program-specific guidance development.

Case Studies

Today. when asked to provide an example of a "good" risk characterization, few people can identify good examples, let alone examples that others would agree are



of high quality. As a first step, a selected number of risk characterization case studies will be developed for use as teaching tools. A "case study" will be an exercise to improve an existing risk characterization, using the information available in an existing risk assessment. While based on actual risk assessments, identifying: information (e.g., site identification information) will be removed to avoid any implied judgement as to the adequacy of the original risk assessment and risk characterization. Examples of case studies may include a chemical assessment, a site-specific assessment. and a screening-level assessment. The case studies will be developed by the risk characterization advisory group, working in consultation with the implementation team, and will be used for discussion at the first risk characterization workshop.

Roundtables and Workshops

EPA decision-makers will be invited to participate in roundtable discussions on risk characterization. In addition. a minimum of two workshops are planned for EPA risk assessors and risk managers.

° *Risk Decision-maker Roundtables on Risk Characterization* - The goal will be to determine the types of risk characterization information needed by managers for effective risk-based decision-making.

° *Risk Characterization Workshop I* - Will focus on identifying the qualities of "good" risk characterizations. program-specific plans and guidance development. and case studies.

° *Risk Characterization Workshop II* - Risk assessors and risk managers will meet to wrap-up program-specific plans and guidance, and discuss any necessary updates to the agency-wide risk characterization guidance.

GUIDANCE FOR RISK CHARACTERIZATION

U.S. Environmental Protection Agency
Science Policy Council
February, 1995

CONTENTS

PREFACE

This guidance contains principles for developing and describing EPA risk assessments, with a particular emphasis on risk characterization. The current document is an update of the guidance issued with the Agency's 1992 policy (Guidance on Risk Characterization for Risk Managers and Risk Assessors, February 26, 1592). The guidance has not been substantially revised, but includes some clarifications and changes to give more prominence to certain issues, such as the. need to explain the use of default assumptions.

As in the 1992 policy, some aspects of this guidance focus on cancer risk assessment, but the guidance applies generally to human health effects (e.g., neurotoxicity, developmental toxicity) and, with appropriate modifications, should be used in all health risk assessments. This document has not been revised to specifically address ecological risk assessment, however, initial guidance for ecological risk characterization is included in EPA's Framework for Ecological Risk Assessments (EPA/630/R-92/001). Neither does this guidance address in detail the use of risk assessment information (e.g., information from the Integrated Risk Information System (IRIS)) to generate site- or media-specific risk assessments. Additional program-specific guidance will be developed to enable implementation of EPA's Risk Characterization 'Policy. Development of such guidance will be overseen by the Science Policy Council and will involve risk assessors and risk managers from across the Agency.

I. THE RISK ASSESSMENT-RISK MANAGEMENT INTERFACE

Recognizing that for many people the term risk assessment has wide meaning, the National Research Council's 1983 report or risk assessment in the federal government distinguished between risk assessment and risk management.

> "Broader uses of the term [risk assessment] than ours also embrace analysis of perceived risks, comparisons of risks associated with different regulatory strategies, and occasionally analysis of the economic and social implications of regulatory decisions -- functions that we assign to risk management (emphasis added). (1)

In 1984, EPA endorsed these distinctions between risk assessment and risk management for Agency use (2), and later relied on them in developing risk assessment guidelines (3). In 1994, the NRC reviewed the Agency's approach to and use of risk assessment and issued an extensive report on their findings (4). This distinction suggests that EPA participants in the process can be grouped into two main categories, each with somewhat.. different responsibilities, based on their roles with respect to risk assessment and risk management.

A. Roles of Risk Assessors and Risk Managers

Within the Risk Assessment category there is a group that develops chemical-specific risk assessments by collecting, analyzing, and synthesizing scientific data to produce the hazard identification, dose-response, and exposure assessment portion of the risk assessment and to characterize risk. This group relies in part on Agency risk assessment guidelines to address science policy issues and scientific uncertainties. Generally, this group includes scientists and statisticians in the Office of Research and Development; the Office of Prevention; Pesticides and Toxics and other program offices; the Carcinogen Risk Assessment Verification Endeavor (CRAVE); and the Reference Dose (RfD) and Reference Concentration (RfC) Workgroups.

Another group generates site- or media-specific risk assessments for use in regulation development or site-specific decision-making. These assessors rely on existing databases (e.g., IRIS, ORD Health Assessment Documents, CRAVE and RfD/RfC Workgroup documents, and program-specific toxicity information) and media- or site-specific exposure information in developing risk assessments. This group also relies in part on Agency risk assessment guidelines and program-specific guidance to address science policy issues and scientific uncertainties. Generally, this group includes scientists and analysts in program offices, regional offices, and the Office of Research and Development.

Risk managers, as a separate category, integrate the risk characterization with other considerations specified in applicable statutes to make and justify regulatory decisions. Generally, this group includes Agency managers and decision-makers. Risk managers also play a role in determining the scope of risk assessments. The risk assessment process involves regular interaction between risk assessors and risk managers, with overlapping responsibilities at various stages in the overall process. Shared responsibilities include initial decisions regarding the planning and conduct of an assessment, discussions as the assessment develops, decisions regarding new data needed to complete an assessment and to address significant uncertainties. At critical junctures in the assessment, such consultations shape the nature of, and schedule for, the assessment. External experts and members of the public may also play a role in determining the scope of the assessment; for example, the public is often concerned about certain chemicals or exposure pathways in the-development of site-specific risk assessments.

B. Guiding Principles

The following guidance outlines principles for those who generate, review, use, and integrate risk assessments for decision-making.

1. Risk assessors and risk managers should be sensitive to distinctions between risk assessment and risk management.

The major participants in the risk assessment process have many shared responsibilities. Where responsibilities differ, it is important that participants confine themselves to tasks in their areas of responsibility and not inadvertently obscure differences between risk assessment and risk management.

For the generators of the assessment, distinguishing between risk assessment and risk management means that scientific information is selected, evaluated, and presented without considering issues such as cost, feasibility, or how the scientific analysis might influence the regulatory or site-specific decision. Assessors are charged with (1) generating a credible, objective, realistic, and scientifically balanced analysis; (2) presenting information on hazard, dose-response, exposure and risk; and (3) explaining confidence in each assessment by clearly delineating strengths, uncertainties and assumptions, along with the impacts of these factors (e.g., confidence limits, use of conservative/ non-conservative assumptions) on the overall assessment. They do not make decisions on the acceptability of any risk level for protecting public health or selecting procedures for reducing risks.

For users of the assessment and for decision-makers who integrate these assessments into regulatory or site-specific decisions, the distinction between risk assessment and risk management means refraining from influencing the risk description through consideration of other factors -- e.g., the regulatory outcome -- and from attempting to shape the risk assessment to avoid statutory constraints, meet regulatory objectives, or serve political purposes. Such management considerations are often legitimate considerations for the overall regulatory decision (see next principle), but they have no role in estimating or describing risk. However, decision-makers and risk assessors participate in an Agency process that establishes policy directions that determine the overall nature and tone of Agency risk assessments and, as appropriate, provide policy guidance on difficult and controversial risk assessment issues. Matters such as risk assessment priorities, degree of conservatism, and acceptability of particular risk levels are reserved for decision-makers who are charged with making decisions regarding protection of public health.

2. The risk assessment product, that is, the risk characterization, is only one of several kinds of information used for regulatory decision-making.

Risk characterization, the last step in risk assessment, is the starting point for risk management considerations and the foundation for regulator decision-making, but it is only one of several important components in such decisions. As the last step in risk assessment, the risk characterization identifies and highlights the noteworthy risk conclusions and related uncertainties. Each of the environmental laws administered by EPA calls for consideration of other factors at various stages in the regulatory process. As authorized by different statutes, decision-makers evaluate technical feasibility (e.g., treatability, detection limits), economic, social,, political, and legal factors as part of the analysis of whether or not to regulate and, if **so,** to what extent. Thus, regulatory decisions are usually based on a combination of the technical analysis used to develop the risk assessment and information from other fields.

For this reason, risk assessors and managers should understand that the regulatory decision is usually not determined solely by the outcome of the risk assessment. For example, a regulatory decision on the use of a particular pesticide considers not only the risk level to affected populations, but also the agricultural benefits of its use that may be important for the nation’s food supply. Similarly, assessment efforts may produce an RfD for a particular chemical, but other considerations may result in a regulatory level that is more or less protective than the RfD itself.

For decision-makers, this means that societal considerations (e.g., costs and benefits) that, along with the risk assessment, shape the regulatory decision should be described as fully as the scientific information set forth in the risk characterization.. Information on data sources and analyses, their strengths and limitations, confidence in the assessment, uncertainties, and alternative analyses are as important here as they are for the scientific components of the regulatory decision. Decision-makers should be able to expect, for example, the same level of rigor from the economic analysis as they receive from the risk analysis. Risk management decisions involve numerous assumptions and uncertainties regarding technology, economics and social factors, which need to be explicitly identified for the decision-makers and the public.

II. RISK CHARACTERIZATION

A. Defining Risk Characterization in the Context of Risk Assessment

EPA risk assessment principles and practices draw on many sources. Obvious sources include the environmental laws administered by EPA, the National Research Council's 1983 report on risk assessment (l), the Agency's Risk Assessment Guidelines (3), and various program specific guidance (e.g., the Risk Assessment Guidance for Superfund). Twenty years of EPA experience in developing, defending, and enforcing risk assessment-based regulation is another. Together these various sources stress the importance of a clear explanation of Agency processes for evaluating hazard, dose-response, exposure, and other data that provide the scientific foundation for characterizing risk.

This section focuses on two requirements for full characterization of risk. First, the characterization should address qualitative and quantitative features of the assessment. Second, it should identify the important strengths and uncertainties in the assessment as part of a discussion of the confidence in the assessment. This emphasis on a full description of all elements of the assessment draws attention to the importance of the qualitative, as well as the quantitative, dimensions of the assessment. The 1983 NRC report carefully distinguished qualitative risk assessment from quantitative assessments, preferring risk statements that are not strictly numerical.

> The term <u>risk assessment</u> is often given narrower and broader meanings than we have adopted here. For some observers, the term is synonymous with quantitative risk assessment and emphasizes reliance on numerical results. Our broader definition includes quantification, but also includes qualitative expressions of risk. Quantitative estimates of risk are not always feasible, and they may be eschewed by agencies for policy reasons. (1)

EPA's Exposure Assessment Guidelines define risk characterization as the final step in the risk assessment process that:

- Integrates the individual characterizations from the hazard identification, dose-response, and exposure assessments;

- Provides an evaluation of the overall quality of the assessment and the degree of confidence the authors have in the estimates of risk and conclusions drawn;

- Describes risks-to individuals and populations in terms of extent and severity of probable harm; and

- Communicates results of the risk assessment to the risk manager. (5)

Particularly critical to full characterization of risk is a frank and open discussion of the uncertainty in the overall assessment and in each of its components. The uncertainty discussion is important for several reasons.

1. Information from different sources carries different kinds of uncertainty and knowledge of these differences is important when uncertainties are combined for characterizing risk.

2. The risk assessment process, with management input, involves decisions regarding the collection of additional data (versus living with uncertainty); in the risk characterization, a discussion of the uncertainties will help to identify where additional information could contribute significantly to reducing uncertainties in risk assessment.

3. A clear and explicit statement of the strengths and limitations of a risk assessment requires a clear and explicit statement of related uncertainties.

A discussion of uncertainty requires comment on such issues as the quality and quantity of available data, gaps in the data base for specific chemicals, quality of the measured data, use of default assumptions, incomplete understanding of general biological phenomena, and scientific judgments or science policy positions that were employed to bridge information gaps.

In short, broad” agreement exists on the importance of a full picture of risk, particularly including a statement of confidence in the assessment and the associated uncertainties. This section discusses information content and uncertainty aspects of risk characterization, while Section III discusses various descriptors used in risk characterization.

B. Guiding Principles

1. **The risk characterization integrates the information from the hazard identification, dose-response, and exposure assessments, using a combination of qualitative information, quantitative information, and information regarding uncertainties.**

Risk assessment is based on a series of questions that the assessor asks about the data and the implications of the data for human risk. Each question calls for analysis and interpretation of the available studies, selection of the data that are most scientifically reliable and most relevant to the problem at hand, and scientific conclusions regarding the question presented. As suggested below, because the questions and analyses are complex, a complete characterization includes several different kinds of information, carefully selected for, reliability and relevance.

a. *Hazard Identification* -- What is known about the capacity of an environmental agent for causing cancer (or other adverse effects) in humans and laboratory animals?

Hazard identification is a qualitative description based on factors such as the kind and quality of data on humans or laboratory animals, the availability of ancillary information (e.g., structure-activity analysis, genetic toxicity, pharmacokinetics) from other studies, and the weight-of-the-evidence from all of these data sources. For example, to develop this description, the issues addressed include:

1) the nature, reliability, and consistency of the particular studies in humans and in laboratory animals;

2) the available information on the mechanistic basis for activity; and

3) experimental animal responses and their relevance to human outcomes.

These issues make clear that the task of hazard identification is characterized by describing the full range of available information and the implications of that information for human health.

b. *Dose-Response Assessment* -- What is known about the biological mechanisms and dose-response relationships underlying any effects observed in the laboratory or epidemiology studies providing data for the assessment?

The dose-response assessment examines quantitative relationships between exposure (or dose) and effects in the studies used to identify and define effects of concern. This information is later used along with "real world" exposure information (see below) to develop estimates-of the likelihood of adverse effects in populations potentiality at risk. It should be noted that, in practice, hazard identification for developmental toxicity and other non-cancer health effects is usually done in conjunction with an evaluation of dose-response relationships, since the determination of whether there is a hazard is often dependent on whether a dose response relationship is present. (6) Also, the framework developed by EPA for ecological risk assessment does not distinguish between hazard identification and dose-response assessment, but rather calls for a "characterization of ecological effects." (7)

Methods for establishing dose-response relationships often depend on various assumptions used in lieu of a complete data base, and the method chosen can strongly influence the overall assessment. The Agency's risk assessment guidelines often identify so-called "default assumptions" for use in the absence of other information. The risk assessment should pay careful attention to the choice of a high-to-low dose extrapolation procedure. As a result, an assessor who is characterizing a dose-response relationship considers several key issues:

1) the relationship between extrapolation models selected and available information on biological mechanisms;

2) how appropriate data sets were selected from those that show the range of possible potencies both in laboratory animals and humans;

3) the basis for selecting interspecies dose scaling factors to account for scaling doses from experimental animals to humans;

4) the correspondence between the expected route(s) of exposure and the exposure route(s) utilized in the studies forming the basis of the dose-response assessment, as well as the interrelationships of potential effects from different exposure routes;

5) the correspondence between the expected duration of exposure and the exposure durations in the studies used in forming the basis of the dose-response assessment, e.g., chronic studies would be used to assess long-term, cumulative exposure concentrations, while acute studies would be used in assessing peak levels of exposure; and

6) the potential for differing susceptibilities among population subgroups.

The Agency's Integrated Risk Information System (IRIS) is a repository for such information for EPA. EPA program offices also maintain program-specific databases, such as the OSWER Health Effects Assessment Summary Tables (HEAST). IRIS includes data summaries representing Agency consensus on specific chemicals, based on a careful review of the scientific issues listed above. For specific risk assessments based on data from any source, risk assessors should carefully review the information presented, emphasizing confidence in the data and uncertainties (see subsection 2 below). Specifically, when IRIS data are used, the IRIS statement of confidence should be included as an explicit part of the risk characterization for hazard and dose-response information.

c. *Exposure Assessment* -- What is known about the principal paths, patterns, and magnitudes of human exposure and numbers of persons who may be exposed?

The exposure assessment examines a wide range of exposure parameters pertaining to the environmental scenarios of people who may be exposed to the agent under study. The information considered for the exposure assessment includes monitoring studies of chemical concentrations in environmental media, food, and other materials; modeling of envirormental fate and transport of contaminants; and information on different activity patterns of different population subgroups. An assessor who characterizes exposure should address several issue::

1) The basis for the values and input parameters used for each exposure scenario. If the values are based on data, there should be a discussion of the quality, purpose, and representativeness of the database. For monitoring data, there should be a discussion of the data quality objectives as they are relevant to risk

assessment, including the appropriateness of the analytical detection limits. If models are applied, the appropriateness of the models and information on their validation should be presented. When assumptions are made, the source and general logic used to develop the assumptions (e.g., program guidance, analogy, professional judgment) should be described.

2) The confidence in the assumptions made about human behavior and the relative likelihood of the different exposure scenarios.

3) The major factor or factors (e.g., concentration, body uptake, duration/frequency of exposure) thought to account for the greatest uncertainty in the exposure estimate, due either to sensitivity or lack of data.

4) The link between the exposure information and the risk descriptors discussed in Section III of this Appendix. Specifically, the risk assessor needs to discuss the connection between the conservatism or non-conservatism of the data/assumptions used in the scenarios and the choice of descriptors.

5) Other information that may be important for the particular risk assessment. For example, for many assessments, other sources and background levels in the environment may contribute significantly to population exposures and should be discussed.

2) The risk characterization includes a discussion of uncertainty and variability.

In the risk characterization, conclusions about hazard and dose response are integrated with those from the exposure assessment. In addition, confidence about these conclusions, including information about the uncertainties associated with each aspect of the assessment in the final risk summary, is highlighted. In the previous assessment steps and in the risk characterization, the risk assessor must distinguish between variability and uncertainty.

Variability arises from true heterogeneity in characteristics such as dose-response differences within a population, or differences in contaminant levels in the environment. The values of some variables used in an assessment change with time and space, or across the population whose exposure is being estimated. Assessments should address the resulting variability in doses received by members of the target population. Individual exposure, dose, and risk can vary widely in a large population. The central tendency and high end individual risk descriptors (discussed in Section III below) are intended to capture the variability in exposure, lifestyles, and other factors that lead to a distribution of risk across a population.

Uncertainty, on the other hand, represents lack of knowledge about factors such as adverse effects or contaminant levels which may be reduced with additional study Generally, risk assessments carry several categories of uncertainty, and each merits consideration. Measurement uncertainty refers to the usual error that accompanies scientific measurements--standard statistical techniques can often be used to express measurement uncertainty. A substantial amount of uncertainty is often inherent in environmental sampling, and assessments should address these uncertainties. There are likewise uncertainties associated with the use of scientific models, e.g., dose-response models, models of environmental fate and transport. Evaluation of model uncertainty would consider the scientific basis for the model and available empirical validation.

A different kind of uncertainty stems from data gaps -- that is, estimates or assumptions used in the assessment. Often, the data gap is broad, such as the absence of information on the effects of exposure to a chemical on humans or on the biological mechanism of action of an agent. The risk assessor should include a statement of confidence that reflects the degree to which the risk assessor believes that the estimates or assumptions adequately fill the data gap, For some common and important data gaps, Agency or program-specific risk assessment guidance provides default assumptions or values. Risk assessors should carefully consider all available data before deciding to rely on default assumptions. If defaults are used, the risk assessment should reference the Agency guidance that explains the default assumptions or values.

Often risk assessors and managers simplify discussion of risk issues by speaking only of the numerical components of an assessment. That is, they refer to the alpha-numeric weight-of-the-evidence classification, unit risk, the risk-specific dose or the q_1^* for cancer risk, and the RfD/RfC for health effects other than cancer, to the exclusion' of other information bearing on the risk case. However, since every assessment carries uncertainties, a simplified numerical presentation of risk is always incomplete and often misleading. For this reason, the NRC (1) and EPA risk assessment guidelines (2) call for “characterizing” risk to include qualitative information, a related numerical risk estimate and a discussion of uncertainties, limitations, and assumptions--default and otherwise.

Qualitative information on methodology, alternative interpretations, and working assumptions (including defaults) is an important component of risk characterization. For example, specifying that animal studies rather than human studies were used in an assessment tells others that the risk estimate is based on assumptions about human response to a particular chemical rather than human data. Information that human exposure estimates are based in the subjects' presence in the vicinity of a chemical accident rather than tissue measurements defines known and unknown aspects of the exposure component of the study.

Qualitative descriptions of this kind provide crucial information that augments understanding of numerical risk estimates. Uncertainties such as these are expected in scientific studies and in any risk assessment based on these studies. Such uncertainties do not reduce the validity of the assessment. Rather, they should be highlighted along with other important risk assessment conclusions to inform others fully on the results of the assessment.

In many cases, assessors must choose among available data, models, or assumptions in estimating risks. Examining the impact of selected, plausible alternatives on the conclusions of the assessment is an important part of the uncertainty discussion. The key words are "selected" and "plausible;" listing all alternatives to a particular assumption, regardless of their merits would be superfluous. Generators of the assessment, using best professional judgment, should outline the strengths and weaknesses of the plausible alternative approaches.[1]

An adequate description of the process of alternatives selection involves several aspects.

a. A rationale for the choice.
b. Discussion of the effects of alternatives selected on the assessment.
c. Comparison with other plausible alternatives, where appropriate.

The degree to which variability and uncertainty are addressed depends largely on the scope of the assessment and the resources available. For example, the Agency does not expect an assessment to evaluate and assess every conceivable exposure scenario for every possible pollutant, to examine all susceptible populations , potentially at risk, or to characterize every possible environmental scenario to estimate the cause and effect relationships between exposure to pollutants and adverse health effects. Rather, the discussion of uncertainty and variability should reflect the type and complexity of the risk assessment, with the level of effort for analysis and discussion of uncertainty corresponding to the level of effort for the assessment.

3. Well-balanced risk characterizations present risk conclusions and information regarding the strengths and limitations of the assessment for other risk assessors, EPA decision-makers, and the public.

The risk assessment process calls for identifying and highlighting significant risk conclusions and related uncertainties partly to assure full communication among risk assessors and partly to assure that decision-makers are fully informed. Issues are identified by acknowledging noteworthy qualitative and quantitative factors that make a difference in the overall assessment of hazard and risk, and hence in the ultimate regulatory decision. The key word is "noteworthy." Information that

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[1] In cases where risk assessments within an Agency program routinely address similar sets of alternatives, program guidance may be developed to streamline and simplify the discussion of these alternatives.

significantly influences the analysis is explicitly noted -- in all future presentations of the risk assessment and in the related decision. Uncertainties and assumptions that strongly influence confidence in the risk estimate also require special attention.

Numerical estimates should not be separated from the descriptive information that is integral to risk characterization. Documents and presentations supporting regulator or site-specific decisions should include both the numerical estimate and descriptive information; in short reports, this information can be abbreviated. Fully visible information assures that important features of the assessment are immediately available at each level of review for evaluating whether risks are acceptable or unreasonable.

III. EXPOSURE ASSESSMENT AND RISK DESCRIPTORS

A. Presentation of Risk Descriptors

The results of a risk assessment are usually communicated to the risk manager in the risk characterization portion of the assessment. This communication is often accomplished through risk descriptors which convey information and answer questions about risk, each descriptor providing different information and insights. Exposure assessment plays a key role in developing these risk descriptors since each descriptor is based in part on the exposure distribution within the population of interest.

The following guidance outlines the different descriptors in a convenient order that should not be construed as a hierarchy of importance. These descriptors should be used to describe risk in a variety of ways for a given assessment, consistent with the assessment's purpose, the data available, and the information the risk manager needs. Use of a range of descriptors instead of a single descriptor enables Agency programs to present a picture of risk that corresponds to the range of different exposure conditions encountered for most environmental chemicals. This analysis, in turn, allows risk managers to identify populations at greater and lesser risk and to shape regulatory solutions accordingly"

Agency risk assessments will be expected to address or 'provide descriptions of (1) individual risk that include the central tendency and high end portions of the risk distribution, (2) population risk, and (3) important subgroups of the population, such as highly exposed or highly susceptible groups. Assessors may also use additional descriptors of risk as needed when these add to the clarity of the presentation. With the exception of assessments where particular descriptors clearly do not apply, some form of these three types of descriptors should be routinely developed and presented for Agency risk assessments. In other cases, where a descriptor would be relevant, but the program lacks the data or methods to develop it, the program office should design and implement a plan, in coordination with other EPA offices, to meet these assessment needs. While gaps continue to exist, risk assessors should make their best efforts to address each risk descriptor, and at a minimum, should briefly discuss the lack of data or methods. Finally, presenters of risk assessment information "should be prepared to routinely answer questions by risk managers concerning these descriptors.

It is essential that presenters not only communicate the results of the assessment by addressing each of the descriptors where appropriate, but that they also

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[2] Program-specific guidance will need to address these situations. For example, for site-specific assessments, the utility and appropriateness of population risk estimates will be determined based on the available data and program guidance.

communicate their confidence that these results portray a reasonable picture of the actual or projected exposures. This task will usually be accomplished by frankly commenting on the key assumptions and parameters that have the greatest impact on the results, the basis or rationale for choosing these assumptions/parameters, and the consequences of choosing other assumptions.

B. Relationship Between Exposure Descriptors and Risk Descriptors

In the risk assessment process, risk is estimated as a function of exposure, with the risk of adverse affects increasing as exposure increases. Information on the levels of exposure experienced by different members of the population is key to understanding the range of risks that may occur. Risk assessors and risk managers should keep in mind, however, that exposure is not synonymous with risk. Differences among individuals in absorption rates, susceptibility, or other factors mean that individuals with the same level of exposure may be at different levels of risk. In most cases, the state of the science is not yet adequate to define distributions of factors such as population susceptibility. The guidance principles below discuss a variety of risk descriptors that primarily reflect differences in estimated exposure. If a full "description of the range of susceptibility in the population cannot be presented, an effort should be made to identify subgroups that, for various reasons, may be particularly susceptible.

C. Guiding Principles

1. **Information about the distribution of <u>individual</u> exposures is important to communicating the results of a risk assessment.**

The risk manager is generally interested in answers to questions such as the following:

- Who are the people at the highest risk?
- What risk levels are they subjected to?
- What are they doing, where do they live, etc., that might be putting them at this higher risk?
- What is the average risk for individuals in the population of interest?

Individual exposure and risk descriptors are intended to provide answers to these questions so as to illuminate the risk management decisions that need to be made. In order to describe the range of risks, both high end and central tendency descriptors are used to convey the variability risk levels experienced by different individuals in the population.

a. High end descriptor

For the Agency's purposes, high end risk descriptors are plausible estimates of the individual risk for those persons at the upper end of the risk distribution. Given limitations in current understanding of variability in individuals' sensitivity to toxins, high end descriptors will usually address high end exposure or dose (herein referred to as exposure for brevity). The intent of these descriptors is to convey estimates of exposure in the upper range of the distribution, but to avoid estimates which are beyond the true distribution. Conceptually, high end exposure means exposure above about the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest exposure. When large populations are assessed, a large number of individuals may be included within the "high end" (e. g., above 90th or 95th percentile) and information on the range of exposures received by these individuals should be presented.

High end descriptors are intended to estimate the exposures that are expected to occur in small, but definable, "high end" segments of the subject population.[3] The individuals with these exposures may be members of a special population segment or individual in the general population who are highly exposed because of the inherent stochastic nature of the factors which give rise to exposure. Where differences in sensitivity can be identified within the population, high end estimates addressing sensitive individuals or subgroups can be developed.

In those few cases in which the complete. data on the population distributions of exposures and doses are available, high end exposure or dose estimates can be represented by reporting exposures or doses at a set of selected percentiles of the distributions, such as the 90th, 95th, and 98th percentile. High end exposures or doses, as appropriate, can then be used to calculate high end risk estimates.

In the majority of cases where the complete distributions are not available, several methods help estimate a high end exposure or dose. If sufficient information about the variability in chemical concentrations, activity patterns, or other factors are available, the distribution may be estimated through the use of appropriate modeling (e.g., Monte Carlo simulation or parametric statistical methods). The

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[3] High end estimates focus on estimates of exposure in the exposed populations. Bounding estimates, on the other hand, are constructed to be equal to or greater than the highest actual risk in the population (or the highest risk that could be expected in a future scenario). A "worst case scenario"' refers to a combination of events and conditions such that, taken together, produces the highest conceivable risk. Although it is possible that such an exposure, dose, or sensitivity combination might occur in a given population of interest, the probability of an individual receiving this combination of events and conditions is usually small, and often so small that such a combination will not recur in a particular, actual population. "

determination of whether available information is sufficient to support the use of probabilistic estimation methods requires careful review and documentation by the risk assessor. If the input distributions are based on limited data, the resulting distribution should be evaluated carefully to determine whether it is an improvement over more traditional estimation techniques. If a distribution is developed, it should be described with a series of percentiles or population frequency estimates, particularly in the high end range. The assessor and risk manager should be aware, however, that unless a great deal is known about exposures and doses at the high end of the distribution, these estimates will involve considerable uncertainty which the exposure assessor will need to describe. Note that in this context, the probabilistic analysis addresses variability of exposure in the population. Probabilistic techniques may also be applied to evaluate uncertainty in estimates (see section 5, below). However, it is generally inappropriate to combine distributions reflecting both uncertainty and variability to get a single overall distribution. Such a result is not readily interpretable for the concerns of environmental decision-making.

If only limited information on the distribution of the exposure or dose factors is available, the assessor should approach estimating the high end by identifying the most sensitive variables and using high end values for a subset of these variables, leaving others at their central values.[4] In doing this, the assessor needs to avoid combinations of parameter values that are inconsistent (e.g., low body weight used in combination with high dietary intake rates), and must keep in mind the ultimate objective of being within the distribution of actual expected exposures and doses, and not beyond it.

If very little data are available on the ranges for the various variables, it will be difficult to estimate exposures or doses and associated risks in the high end with much confidence. One method that has been used in such cases is to start with a bounding estimate and “back off’ the limits used until the combination of parameter values is, in the judgment of the assessor, within the distribution of expected exposure, and still lies within the upper 10% of persons exposed. Obviously, this method results in a large uncertainty and requires explanation.

b. Central tendency descriptor

Central tendency descriptors generally reflect central estimates of exposure or dose. The descriptor addressing central tendency may be based on either the arithmetic mean exposure (average estimate) or the median exposure (median estimate), either

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[4] Maximizing all variables will in virtually all cases result in an estimate that is above the actual values seen in the population. When the principal parameters of the dose equation, e.g., concentration (appropriately integrated over time), intake rate, and duration, are broken out into sub-components, it may be necessary to use maximum values for more than two of these sub-component parameters, depending on a sensitivity analysis.

of which should be clearly labeled. The average estimate, used to approximate the arithmetic mean, can often be derived by using average values for all the exposure factors.[5] It does not necessarily represent a particular individual on the distribution. Because of the skewness of typical exposure profiles, the arithmetic mean may differ substantially from the median estimate (i.e., 50th percentile estimate, which is equal to the geometric mean for a log normal distribution). The selection of which descriptor(s) to present in the risk characterization will depend on the available data and the goals of the assessment. When data are limited, it may not be possible to construct true median or mean estimates, but it is still possible to construct estimates of central tendency. The discussion of the use of probabilistic techniques in Section l(a) above also applies to estimates of central tendency.

2. Information about population exposure leads to another important way to describe risk.

Population risk refers to an assessment of the extent of harm for the population as a whole. In theory, it can be calculated by summing the individual risks for all individuals within the subject population. This task, of course, requires a great deal more information than is normally, if ever, available.

The kinds of questions addressed by descriptors of population risk include the following:

- How many cases of a particular health effect might be probabilistically estimated in this population for a specific time period?

- For non-carcinogens, what portion of the population is within a specified range of some reference level; e.g., exceedance of the RfD (a dose), the RfC (a concentration), or other health concern level?

- For carcinogens, what portion of the population is above a certain risk level, such as 10^{-6}?

These questions can lead to two different descriptors of population risk.

a. Probabilistic number of *cases*

The first descriptor is the probabilistic number of health effect cases estimated in the population of interest over a specified time period. This descriptor can be obtained either by (a) summing the individual risks over all the individuals in the population, e.g. using an estimated distribution of risk in the population, when

[5] This holds true when variables are added (e. g., exposures by different routes) or when independent variables are multiplied (e.g., concentration x intake). However, it would be incorrect for products of correlated variables, variables used as divisors, or for formulas involving exponents.

such information is available, or (b) through the use of a risk model that assumes a linear non-threshold response to exposure, such as many carcinogenic models. In these calculations, data will typically be available to address variability in individual exposures. If risk varies linearly with exposure, multiplying the mean risk by the population size produces an estimate of the number of cases.[6] At the present time, most cancer potency values represent plausible upper bounds on risk. When such a value is used to estimate numbers of cancer cases, it is important to understand that the result is also an upper bound. As with other risk descriptors, this approach may not adequately address sensitive subgroups for which different dose-response curve or exposure estimates might be needed.

Obviously, the more information one has, the more certain the estimate of this risk descriptor, but inherent uncertainties in risk assessment methodology place limitations on the accuracy of the estimate. The discussion of uncertainty involved in estimating the number of cases should indicate that this descriptor is not to be confused with an actuarial Prediction of cases in the population (which is a statistical prediction based on a great deal of empirical data).

In general, it should be recognized that when small populations are exposed, population risk estimates may be very small For example, if 100 people are exposed to an individual lifetime cancer risk of 10^{-4}, the expected number of cases is 0.01. In such situations, individual risk estimates will usually be a more meaningful parameter for decision-makers.

b. Estimated percentage of population with risk greater than some level

For non-cancer effects, we generally have not developed the risk assessment techniques to the point of knowing how to add risk probabilities, so a second descriptor is usually more appropriate: An estimate of the percentage of the population, or the number of persons, above a specified level of risk or within a specified range of some reference level, e.g., exceedance of the RfD or the RfC, LOAEL, or other specific level of interest. This descriptor must be obtained through measuring or simulating the population distribution.

3. **Information about the distribution of exposure and risk for different subgroups of the population are important components of a risk assessment.**

A risk manager might also ask questions about the distribution of the risk burden among various segments of the subject population such as the following: How do exposure and risk impact various subgroups?; and, what is the population risk of a

[6] However, certain important cautions apply (see EPA's Exposure Assessment Guidelines). Also, this is not appropriate for non-carcinogenic effects or for other types of cancer models. For non-linear cancer models, an estimate of population risk must be calculated using the distribution of individual risks.

particular subgroup? Questions about the distribution of exposure and risk among such population segments require additional risk descriptors.

a. Highly exposed

Highly exposed subgroups can be identified, and where possible, characterized and the magnitude of risk quantified. This descriptor is useful when there is (or is expected to be) a subgroup experiencing significantly different exposures or doses from that of the larger population. These sub-populations may be identified by age, sex, lifestyle, economic factors, or other demographic variables. For example, toddlers who play in contaminated soil and high fish consumers represent sub-populations that may have greater exposures to certain agents.

b. Highly susceptible

Highly susceptible subgroups can also be identified, and if possible, characterized and the magnitude of risk quantified. This descriptor is useful when the sensitivity or susceptibility to the effect for specific subgroups is (or is expected to be) significantly different from that of the larger population. In order to calculate risk for these subgroups, it will sometimes be necessary to use a different dose-response relationship; e.g., upon exposure to a chemical, pregnant women, elderly people, children, and people with certain illnesses may each be more sensitive than the population as a whole. For example, children are thought to be both highly exposed and highly susceptible to the effects of environmental lead. A model has been developed that uses data on lead concentrations in different environmental media to predict the resulting blood lead levels in children. Federal agencies are working together to develop” specific guidance on blood lead levels that present risks to children.

It is important to note, however, that the Agency’s current methodologies for developing reference doses and reference concentrations (RfDs and RfCs) are designed to protect sensitive populations. If data on sensitive human populations are available (and there is confidence in the quality of the data), then the RfD is set at the dose level at which no adverse effects are observed in the sensitive population (e.g., RfDs for fluoride and nitrate). If no such data are available (for example, if the RfD is developed using data from humans of average or unknown sensitivity) then an additional 10-fold factor is used to account for variability between the average human response and the response of more sensitive individuals.

Generally, selection of the population segments is a matter of either a priori interest in the subgroup (e.g., environmental justice considerations), in which case the risk assessor and risk manager can jointly agree on which subgroups to highlight, or a matter of discovery of a sensitive or highly exposed subgroup during the assessment process. In either case, once identified, the subgroup can be treated as a population in itself, and characterized in the same way as the larger population using the descriptors for population and individual risk.

4. Situation-specific information adds perspective on possible future events or regulatory options:

"What if...?" questions can be used to examine candidate risk management options. For example, consider the following:

- What if a pesticide applicator applies this pesticide without using protective equipment?

- What if this site becomes residential in the future?

- What risk level will occur if we set the standard at 100 ppb?

Answering these "What if...?" questions involves a calculation of risk based on specific combinations of factors postulated within the assessment[7]. The answers to these "What if...?" questions do not, by themselves, give information about how likely the combination of values might be in the actual population or about how many (if any) persons might be subjected to the potential future risk. However, information on the likelihood of the postulated scenario would also be desirable to include in the assessment.

When addressing projected changes for a population (either expected future developments or consideration of different regulatory options), it is usually appropriate to calculate and consider all the risk descriptors discussed above. When central tendency or high end estimates are developed for a future scenario, these descriptors should reflect reasonable expectations about future activities. For example, in site-specific risk assessments, future scenarios should be evaluated when they are supported by realistic forecasts of future land use, and the risk descriptors should be developed within that context.

5. An evaluation of the uncertainty in the risk descriptor is an important component of the uncertainty discussion in the assessment.

Risk descriptors are intended to address variability of risk within the population and the overall adverse impact on the population. In particular, differences between high end and central tendency estimates reflect variability in the population, but not the scientific uncertainty inherent in the risk estimates. As discussed above, there

7 Some programs routinely develop future scenarios as part of developing a risk assessment. Program-specific guidance may address future scenarios in more detail than they are described here.

will be uncertainty in all estimates of risk. These uncertainties can include measurement uncertainties, modeling uncertainties, and assumptions to fill data gaps. Risk assessors should address the impact of each of these factors on the confidence in the estimated risk values.

Both qualitative and quantitative evacuations of uncertainty provide useful information to users of the assessment. The techniques of quantitative uncertainty analysis are evolving rapidly and both the SAB (8) and the NRC (4) have urged the Agency to incorporate these techniques into its risk analyses. However, it should be noted that a probabilistic assessment that uses only the assessor's best estimates for distributions of population variables addresses variability, but not uncertainty. Uncertainties in the estimated risk distribution need to be separately evaluated.

REFERENCES

1. National Research Council. Risk Assessment in the Federal Government: Management the Process, 1983.

2. U.S. EPA. Risk Assessment and Management: Framework for Decision Making, 1984.

3. U.S. EPA. "Risk Assessment Guidelines." 51 Federal Register, 33992-34054, September 24, 1986.

4. National Research Council. Science and Judgement in Risk Assessment. 1994.

5. U.S. EPA "Guidelines for Exposure Assessment." 57 Federal Register, 22888-22938, May 29, 1992.

6. U.S. EPA. "Guidelines for Developmental Toxicity Risk Assessment." 56 Federal Register 67398-63826, December 5, 1991.

7. U.S. EPA. Framework for Ecological Risk Assessment. 1992.

8. Loehr, R. A., and Matanoski, G. M., Letter to Carol M. Browner, EPA Administrator, Re: Quantitative Uncertainty Analysis for Radiological Assessments. EPA Science Advisory Board, July 23, 1993 (EPA-SAB-WC-COM-93-006).